

## INTERNATIONAL SEARCH REPORT

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<b>A. CLASSIFICATION OF SUBJECT MATTER</b>																				
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<b>B. FIELDS SEARCHED</b>																				
Minimum documentation searched (classification system followed by classification symbols) U.S. : .128/DIG. 12: 222/94-96: 604/131, 132, 151, 153, 185, 257, 259, 262, 890.1																				
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Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) APS, IS&R																				
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>																				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.																		
Y, P	US 5,693,018 A (KRIESEL ET AL.) 02 DECEMBER 1998, ENTIRE REFERENCE, AND ESPECIALLY FIGS. 4, 7, 17 AND 19	1-5, 11-14, 16-18, 23-29, 33-41, 46, 48, 49																		
Y	US 5,403,893 A (TANAKA ET AL.) 04 APRIL 1995, ENTIRE REFERENCE, ESPECIALLY FIG. 6.	1, 11, 23, 33, 46, 51																		
Y	US 5,368,570 A (THOMPSON ET AL.) 29 NOVEMBER 1994, FIGS. 1, 2 AND 5.	4, 17, 18, 24, 40, 41																		
Y	US 5,651,979 A (RON ET AL.) 29 JULY 1997, ABSTRACT, AND CLAIM 6.	1, 11, 23, 33, 46, 51																		
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.																				
<table border="0"> <tr> <td>* Special categories of cited documents:</td> <td>*T</td> <td>later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>*A* document defining the general state of the art which is not considered to be of particular relevance</td> <td>*X*</td> <td>document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>*E* earlier document published on or after the international filing date</td> <td>*Y*</td> <td>document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>*A*</td> <td>document member of the same patent family</td> </tr> <tr> <td>*C* document referring to an oral disclosure, use, exhibition or other means</td> <td></td> <td></td> </tr> <tr> <td>*P* document published prior to the international filing date but later than the priority date claimed</td> <td></td> <td></td> </tr> </table>			* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	*A* document defining the general state of the art which is not considered to be of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	*E* earlier document published on or after the international filing date	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A*	document member of the same patent family	*C* document referring to an oral disclosure, use, exhibition or other means			*P* document published prior to the international filing date but later than the priority date claimed		
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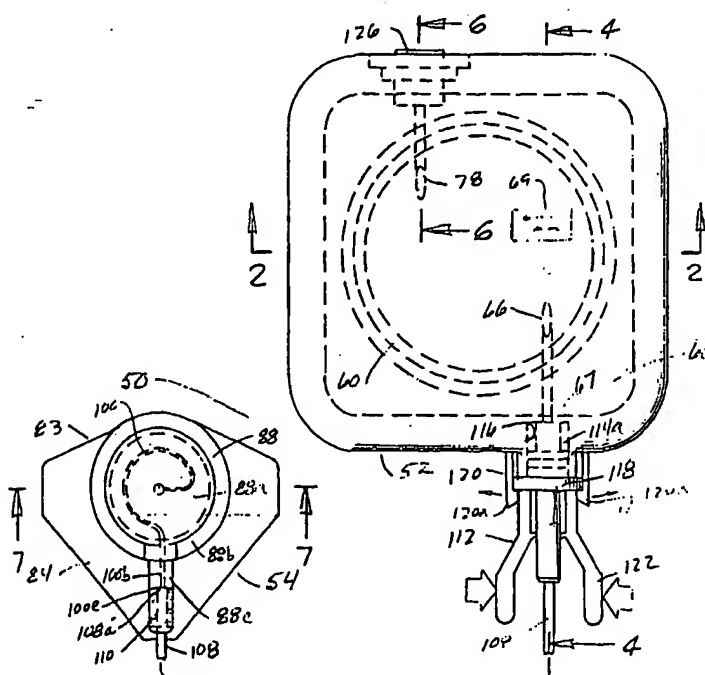
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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US98/17766 (22) International Filing Date: 27 August 1998 (27.08.98) (30) Priority Data: 08/919,147 27 August 1997 (27.08.97) US (71) Applicant: SCIENCE INCORPORATED [US/US]; Minnesota Center, Suite 1060, 7760 France Avenue South, Bloomington, MN 55435-5803 (US). (72) Inventors: KRIESEL, Marshall, S.; 80 N. Mississippi Road, Saint Paul, MN 55104 (US). THOMPSON, Thomas, N.; 6300 Wentworth, Richfield, MN 55435 (US). (74) Agent: ORUM, Keith, H.; Dvorak & Orum, 53 West Jackson Boulevard, Chicago, IL 60604 (US).			(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  Published With international search report.
(54) Title: FLUID DELIVERY DEVICE WITH TEMPERATURE CONTROLLED ENERGY SOURCE			

## (57) Abstract

A fluid delivery apparatus (50) for infusing medicinal fluids into a patient which is of a compact, low profile, fluid storage device (52), laminate construction, with a cooperating and remotely located infusion means (54) for infusing the medicinal fluid (F) into the patient. The apparatus embodies a novel thermal expanding polymer material (70) which uniquely functions as an internal energy source for expelling the medicinal fluids from the device. The apparatus can be used for subdermal, intradermal and intramuscular infusion of fluids and in one form of the invention, includes a novel delivery cannula having a body portion disposed within a circuitous channel (108) formed within the base (56) of the apparatus and a pierceable portion (100d) which extends outwardly from the base of the apparatus.



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**FLUID DELIVERY DEVICE WITH TEMPERATURE  
CONTROLLED ENERGY SOURCE****SPECIFICATION****Background of the Invention****Field of the Invention**

The present invention relates generally to fluid delivery devices. More particularly, the invention concerns an improved apparatus for infusing medicinal agents into an ambulatory patient at specific rates over extended periods of time.

**Discussion of the Invention**

The oral route is the most frequent route of drug administration. Oral administration is relatively easy for most patients and rarely causes physical discomfort. However, many medicinal agents require a parenteral route of administration thus bypassing the digestive system and precluding degradation by the catalytic enzymes in the digestive tract and the liver.

The use of more potent medications at elevated concentrations has also increased the need for accuracy in controlling the delivery of such drugs. The delivery device, while not an active pharmacologic agent, may enhance the activity of the drug by mediating its therapeutic effectiveness. Certain classes of new pharmacologic agents possess a very narrow range of therapeutic effectiveness, for instance, too small a dose results in no effect, while too great a dose results in toxic reaction.

In the past, prolonged infusion of fluids has generally been accomplished using gravity flow means coupled with electronic based controls and typically involve the use of intravenous



administration sets and the familiar bottle or solution bag suspended above the patient. Such methods are cumbersome, imprecise and, generally non-ambulatory requiring bed confinement of the patient. Periodic monitoring of the apparatus by the nurse or doctor is required to detect malfunctions of the infusion apparatus.

Devices of the character from which liquid is expelled from a relatively thick-walled bladder by internal stresses within the distended bladder have also been suggested for infusion of medicaments. For example, such bladder, or "balloon" type devices, are described in U.S. Patent No. 3,469,578, issued to Bierman and in U.S. Patent No. 4,318,400, issued to Perry.

A family of highly unique fluid delivery devices has been developed by the present inventor. These novel devices make use of recently developed elastomeric films, expandable foams and similar materials, which, in cooperation with a base define a fluid chamber that contains the fluid to be dispensed. The elastomeric film membrane or the expandable member controllably forces fluid within the chamber into outlet fluid flow channels provided in the device. Elastomeric film membrane devices are described in detail in U. S. Patent No. 5,205,820 issued to the present inventor. U. S. Patent No. 5,468,226, also issued to the present inventor, describes various types of expandable cellular elastomers and elastomeric foams used as the energy source of the fluid delivery device for expelling fluid from various physical forms of the fluid delivery device. Because of the pertinence of Patent Nos. 5,205,820 and 5,468,226, these patents are hereby incorporated herein by reference in their entirety as though fully set forth herein. Co-pending U. S. Application Serial No. 08/541,030, filed October 11, 1996 in which the present inventor is named as co-inventor, is also pertinent to one form of the apparatus of the invention which is described hereinafter. Accordingly, Serial No. 08/541,030 is incorporated by reference as though fully set forth herein

The apparatus of the present invention, which takes various physical forms, makes use of a novel temperature expansive material as an energy source. This family of devices can also be used with minimal professional assistance in an alternate health care environment, such as the home. By way of example, devices of the invention can be comfortably and conveniently removably affixed to the patient's body and can be used with or without separate infusion sets for the continuous infusion of antibiotics, hormones, steroids, blood clotting agents, analgesics, and like medicinal agents. Similarly, the devices can be used for I-V chemotherapy and can accurately deliver fluids to the patient in precisely the correct quantities and at extended microfusion rates over time.

One of the embodiments of the present invention comprises an ambulatory fluid dispensing system which includes a relatively thin body attached base assembly and a stored energy means for controllably expelling fluid from the reservoir of the device is provided in the form of a heat expandable gel, the nature of which will be described in greater detail hereinafter. In this particular form of the invention, a novel subcutaneous infusion set can be quickly coupled to the base assembly to enable precise infusion of fluid to a patient upon an increase in temperature of the expandable gel caused by the normal body temperature of the patient. Alternatively, in other embodiments of the invention, infusion is accomplished by infusion means integrally formed with the base assembly.

In other embodiments of the invention which also use a heat expandable gel as an energy source, medicinal fluids are delivered to the patient from the fluid dispenser via various types of infusion means. By way of example, such dispensers can accomplish parenteral administration of a beneficial agent by the subcutaneous, subdermal, intradermal, intramuscular or intravenous routes. Subcutaneous injection places the drug into the tissues

between the skin and the muscle. Drugs administered in this manner are absorbed somewhat slowly. When the beneficial agent is administered subcutaneously, the needle can be inserted at a 45 degree angle or, in some cases, as with obese patients, at a 90 degree angle.

A beneficial agent administered by the intravenous route is given directly into the blood by a needle inserted into a vein. In such instances, action occurs almost immediately.

An intramuscular injection is the administration of a beneficial agent into a muscle. Agents given by this route are absorbed more rapidly than those given by the subcutaneous route. In addition, a larger volume (1-5mL) can be given at one site.

The sites for intramuscular administration are the deltoid muscle (upper arm), the ventrogluteal or dorsogluteal sites (hip), and the vastus lateralis (thigh).

When giving a beneficial drug by the intramuscular route, the needle of the infusion means is preferably inserted at a 90 degree angle.

In all instances, the thrust of the inventions described herein is to provide novel fluid delivery devices which are of low profile and are eminently capable of meeting even the most stringent of fluid delivery tolerance requirements. In this regard, medical and pharmacological research continues to reveal the importance of the manner in which a medicinal agent is administered. The delivery device, while not an active pharmacological agent, may enhance the activity of the drug by mediating its therapeutic effectiveness. For example, certain classes of pharmacological agents possess a very narrow dosage range of therapeutic effectiveness, in which case too small a dose will have no effect, while too great a dose can result in toxic reaction. In other instances, some forms of medication require an extended delivery time to achieve the utmost effectiveness of a medicinal therapeutic regimen.

### Summary of the Invention

It is an object of the present invention to provide a fluid delivery apparatus for infusing medicinal fluids into a patient which is of a compact, low profile, laminate construction. More particularly, it is an object of the invention to provide an apparatus of such a character which embodies a novel thermal expanding polymer material which uniquely functions as an internal energy source for expelling the medicinal fluids from the device.

Another object of the invention is to provide an ambulatory fluid delivery apparatus which can conveniently be used for the precise infusion of various pharmaceutical fluids into an ambulatory patient at controlled rates over extended periods of time.

Another object of the invention is to provide an apparatus of the aforementioned character which is highly reliable and easy-to-use by lay persons in a non-hospital environment.

Another object of the invention is to provide an apparatus as described in the preceding paragraphs which can be used for subdermal, intradermal and intramuscular infusion of fluids.

In this regard, in one form of the invention, the apparatus includes a novel and unique delivery cannula having a body portion disposed within a circuitous channel formed within the base superstructure of the apparatus and a pierceable portion which extends outwardly from the base of the apparatus. By constructing the cannula in a circuitous configuration and dynamically connecting it to the base movement of the cannula relative to the base is permitted thereby minimizing needle related tissue necrosis.

Another object of the invention is to provide an apparatus which embodies a soft, pliable, semi-solid, heat-expandable mass which is heated by the patient's body temperature and when so heated overtime serves as an energy source for expelling fluid from the device

and also functions to provide a conformable ullage within the reservoir of the device which will effectively avoid extended flow delivery rate trail-off at the end of the fluid delivery period.

Another object of the invention is to provide an apparatus as described in the preceding paragraph in which the heat expandable mass is specifically tailored to provide precise predictable protocol delivery of the medicinal agent.

Another object of the invention is to provide an apparatus as described in the preceding paragraph which includes novel means for indicating fluid flow from the reservoir and for indicating the presence of fluid within the reservoir.

A further object of the invention is to provide a low profile, fluid delivery low profile body attaching fluid delivery device of laminate construction which can meet even the most stringent fluid delivery tolerance and flow signature requirements.

Another object of the invention is to provide an apparatus of the class described which includes a temperature controlled, stored energy source that can be constructed from various types of polymeric conformable materials such as phase transition gels.

Another object of the invention is to provide an apparatus of the character described which includes a novel combination filter and rate control assemblage disposed intermediate the fluid reservoir and the outlet port of the device or intermediate outlet port of the device and the infusion means.

Another object of the invention is to provide an apparatus of the character described which, due to its unique construction, can be manufactured inexpensively in large volume by automated machinery.

Other object of the invention are set forth in U.S. Patent Nos. 5,205,820 and 5,468,226, which patents are incorporated herein by reference. Still further objects of the invention will become more apparent from the discussion which follows.

### **Brief Description of the Drawings**

Figure 1 is a top plan view of one form of the fluid delivery apparatus of the invention.

Figure 2 is an enlarged, cross-sectional view taken along lines 2-2 of Figure 1.

Figure 3 is an enlarged, cross-sectional view similar to Figure 2 but showing the heat expandable means of the device in an expanded configuration which will cause the fluid within the reservoir of the device to be controllably expelled therefrom.

Figure 4 is an enlarged, cross-sectional view taken along lines 4-4 of Figure 1 but showing the heat expandable means in an expanded configuration.

Figure 5 is an enlarged, side-elevational, cross-sectional exploded view of the apparatus shown in Figure 2.

Figure 6 is an enlarged, cross-sectional view taken along lines 6-6 of Figure 1, but showing the heat expandable mass in an expanded configuration.

Figure 7 is an enlarged, cross-sectional view taken along lines 7-7 of Figure 1.

Figure 8 is a top plan view of an alternate form of the fluid delivery apparatus of the invention.

Figure 9 is an enlarged, cross-sectional view taken along lines 9-9 of Figure 9.

Figure 10 is a fragmentary, generally perspective view of the outlet portion of the

device better showing the construction of the quick disconnect coupling mechanism of this latest form of the invention.

Figure 11 is a fragmentary, side-elevational view of the apparatus better showing the configuration of the fluid inlet port of the device.

Figure 12 is an enlarged, side-elevational, cross-sectional, exploded view of the apparatus shown in Figure 9.

Figure 12A is an enlarged fragmentary view of the area designated as 12A in Figure 12.

Figure 13 is a top plan view of still another form of the fluid delivery apparatus of the invention.

Figure 14 is an enlarged, cross-sectional view taken along lines 14-14 of Figure 13.

Figure 15 is an enlarged, side-elevational, cross-sectional, exploded view of the device shown in Figure 14.

Figure 16 is a top plan view of yet another of the fluid delivery apparatus of the invention.

Figure 17 is an enlarged, cross-sectional view taken along lines 17-17 of Figure 16.

Figure 18 is an enlarged, side-elevational, cross-sectional, exploded view of the device shown in Figure 17.

Figure 19 is a top plan view of yet another alternate form of the device of the invention.

Figure 20 is an enlarged, cross-sectional view taken along lines 20-20 of Figure 19.

Figure 21 is a top plan view of one form of the infusion set of the invention shown interconnected with the form of the quick coupler mechanism of the invention shown in Figure

19.

Figure 22 is a side-elevational, cross-sectional, exploded view of the apparatus shown in Figure 20.

Figure 23 is an enlarged, cross-sectional view taken along lines 23-23 of Figure 19.

Figure 24 is an enlarged, cross-sectional view taken along lines 24-24 of Figure 19.

Figure 25 is a top plan view of another form of the fluid delivery apparatus of the invention in which the delivery of fluid to the patient is accomplished through the use of a novel cannula carried by the base of the apparatus.

Figure 26 is a cross-sectional view taken along lines 26-26 of Figure 25.

Figure 27 is a generally perspective, exploded, view of the apparatus shown in Figure 26.

Figure 28 is a generally perspective bottom view of the form of the apparatus shown in Figure 25.

Figure 29 is a side-elevational view of the apparatus shown in Figure 25.

Figure 30 is a top plan view of still another form of the fluid delivery apparatus of the invention.

Figure 31 is an enlarged, cross-sectional view taken along lines 31-31 of Figure 29.

Figure 31A is a generally perspective view of one form of the flow indicator element of the device for indicating fluid flow.

Figure 31B is a cross-sectional view of a fluid delivery device similar to that shown in Figure 31, but embodying a slightly different flow indicator element.

Figure 31C is a generally perspective view of the flow indicator element shown in Figure 31B.



Figure 32 is an enlarged, cross-sectional view taken along lines 32-32 of Figure 29.

Figure 33 is a fragmentary, cross-sectional view of the portion of the device identified in Figure 32 by the numeral 33.

Figure 34 is a fragmentary view taken along lines 34-34 of Figure 33.

Figure 35 is a fragmentary view taken along lines 35-35 of Figure 33.

Figure 36 is a generally perspective, exploded view of the device shown in Figure 30.

Figure 37 is an enlarged, fragmentary, generally perspective view of the outlet and cannula cover portions of the apparatus shown in Figure 36.

Figure 38 is a side-elevational view of an alternate form of the cannula and frit assembly of the device.

Figure 39 is a side-elevational view of another embodiment of cannula and frit assembly of the invention.

Figure 40 is a side-elevational view of still another alternate form of the cannula and frit assembly of the device.

Figure 41 is a top plan view of still another form of the fluid delivery apparatus of the invention.

Figure 42 is an enlarged, cross-sectional view taken along lines 42-42 of Figure 41.

Figure 43 is a top plan view of yet another of the fluid delivery apparatus of the invention.

Figure 44 is an enlarged, cross-sectional view taken along lines 44-44 of Figure 43.

Figure 45 is an enlarged, cross-sectional view taken along lines 45-45 of Figure 44.

Figure 46 is an enlarged cross-sectional view of the rate control member of this latest form of the invention.

Figure 47 is a cross-sectional view taken along lines 47-47 of Figure 46.

Figure 48 is a top plan view of still another form of the fluid delivery apparatus of the invention.

Figure 49 is an enlarged, cross-sectional view taken along lines 49-49 of Figure 48.

Figure 50 is a side-elevational, cross-sectional, exploded view of the apparatus shown in Figure 49.

Figure 51 is an enlarged, cross-sectional view taken along lines 51-51 of Figure 50.

Figure 52 is a greatly enlarged fragmentary cross-sectional view of the heat expandable means of this latest form of the invention.

Figure 53 is a top plan view of an alternate form of the fluid delivery apparatus of the invention.

Figure 54 is a cross-sectional view taken along lines 54-54 of Figure 53.

Figure 55 is a cross-sectional view taken along lines 55-55 of Figure 53.

Figure 56 is an enlarged, cross-sectional view taken along lines 56-56 of Figure 53.

Figure 56A is a cross-sectional view similar to Figure 56 but showing the release button of the device in a depressed configuration.

Figure 57 is a cross-sectional view taken along lines 57-57 of Figure 53.

Figure 58 is an enlarged fragmentary view of the upper right-hand portion of Figure 53 showing the details of construction of a portion of the fill means of the invention.

Figure 59 is a generally perspective, exploded view of the apparatus shown in Figure 53.

Figure 60 is a top plan exploded view of the fill vial assembly of the invention.

Figure 61 is a side-elevational view of the fluid storage device of the invention shown

in Figure 53.

Figure 62 is an enlarged end view of an alternate form of the fill needle portion of the fill means of the invention.

Figure 63 is a cross-sectional view taken along lines 63-63 of Figure 62.

Figure 64 is a top plan view of still another form of the fluid delivery apparatus of the invention which embodies a dynamically mounted cannula.

Figure 65 is a cross-sectional view taken along lines 65-65 of Figure 64.

Figure 66 is a cross-sectional view taken along lines 66-66 of Figure 64.

Figure 67 is an enlarged, cross-sectional view taken along lines 67-67 of Figure 64.

Figure 68 is a side-elevational view of the apparatus of the invention shown in Figure 64.

Figure 69 is a generally perspective, exploded view of the apparatus shown in Figure 64.

### Description of the Invention

Referring to the drawings and particularly to Figures 1 through 7, one form of the apparatus of the invention for use in the infusion of medicinal fluids into a patient is there shown and generally designated by the numeral 50. As best seen by referring to Figure 1, the embodiment of the invention there shown comprises a low-profile, fluid storage device 52 and a cooperating infusion means 54 for infusing the fluid stored in device 52 into the patient.

Turning particularly to Figures 2 and 5, it can be seen that fluid storage device 52

includes a thin base 56 having a central portion 56a and peripheral portion 56b circumscribing central portion 56a. Base 56 is provided with a lower surface 56c which engagable with the patient when the device is taped or otherwise removably affixed to the patient such as by pad 58 having an adhesive on both sides of the pad. Formed within base 56 is a circular shaped chamber 60 (Figures 1 and 5), the purpose of which will presently be described.

Comprising an extremely important aspect of the apparatus of the present invention is a heat-expandable means which is carried within chamber 60 of base 56 for causing the fluids contained within the sealed reservoir 64 of the device (Figure 2) to flow outwardly through an outlet 66 formed in the cover 68 which is superimposed over and connected to base 56 in the manner shown in Figures 1, 2, and 3. The heat-expandable means is here provided in the form of a thermal expandable polymer mass 70 which is disposed within chamber 60 in the manner best seen in Figure 2.

Expandable mass 70 can take several forms, but a particularly attractive form for devices of the present invention comprises a semisolid form such as a gel. Unlike a liquid, which can offer no permanent resistance to change in shape and must be constrained within some type of container, expandable mass 70 is of a semisolid form which can be handled without external containment under ambient manufacturing conditions. Gels are sometimes characterized soft solids and reside in a state between a liquid and a solid state and typically comprise a cross-linked network of long polymer molecules with liquid molecules trapped within the network. Many gels known in the prior art not only are capable of significantly large volume change in response to stimulus (phase-transition gels), but also exhibit physical characteristics that enable them to closely conform to the shape of an adjacent member such as a distensible membrane. Such gels are ideally suited for use as conformable ullages within the

fluid reservoir of fluid delivery devices of the character described hereinafter and also of the character described in incorporated-by-reference application Serial No. 08/541,030. As discussed in the aforementioned application, the conformable ullage characteristics of the gel assist in insuring the complete and controlled expelling of fluids from the reservoir of the delivery device.

Phase transition gels suitable for use in constructing the heat expandable means of the present invention are gels which exhibit a phase transition at a phase-transition condition. The difference in volume between the expanded phase of phase-transition gels and the contracted phase thereof can be orders of magnitude. Examples of phase-transition gels are disclosed in Tanaka et al., U.S. Patent No. 4,732,930; No. Re-35068 and No. 5,403,893. Because of the pertinence of these patents, Patent No. 4,732,930, Patent No. 5,403,893 and Patent No. Re-35068 are all hereby incorporated by reference as though fully set forth herein. While a number of the phase transition gels described in the Tanaka et al patents can be used to construct the heat expandable mass of the present invention, the ionized acrylamide gel compositions therein described are capable of quite drastic volume change in response to an external stimulus such as the body temperature of the patient. These ionized acrylamide gel compositions comprise a cross-link, partially ionized polyacrylamide gel wherein between up to 20% of the amide groups are hydrolyzed to carboxyl groups. The gel includes a solvent of a critical concentration at which a slight change in temperature, pH or salt concentration causes the gel to shrink or swell drastically. As pointed out by Tanaka et al, the particular critical concentration utilized in the gel composition depends upon the solvent employed, the temperature of the gel and the degree of hydrolysis of the gel. The gel also can contain a positive metal ion such as sodium or magnesium which has the effect of increasing the change

in gel volume caused by change of solvent concentration, temperature, pH or, salt concentration.

Another form of phase-transition gel suitable for use in the devices of the present invention comprises interpenetrating polymer networks which include a first polymer and a second polymer, wherein the second polymer interpenetrates the first polymer. Suitable first and second polymers include polymers which can interact during exposure to a phase-transition condition to thereby cause a significantly large volume change of the gel. Suitable interpenetrating polymer networks can also include more than two polymers. For example, additional polymers can be included which interpenetrate the first and/or second polymers. The nature of the polymers as well as interaction between the polymers is discussed in detail in Tanaka, U. S. Patent No. 5,403,893, and will not here be repeated.

Turning particularly to Figure 2, it is to be noted that sealing means are superimposed over chamber 60 and expandable mass 70 to seal chamber 60. This sealing means here comprises a distendable membrane 72 which is sealably connected to the peripheral portion 56d of base 56 in the manner shown in Figures 2 and 3. Overlaying membrane 72 is a distendable membrane 74 which, in cooperation with a generally concave shaped cavity 68a formed in cover 68, forms fluid reservoir 64 (Figure 2). It is to be understood that the reservoir defining cavity can be of any desired geometry. More particularly, as best seen in Figure 2, membrane 72 sealably covers chamber 60 and mass 70 while membrane 74 overlays sealing membrane 72 and is bonded to cover 68. This construction enables membrane slip, that is the ability of the membranes to move relative to each other. In a manner presently to be described, fill means are provided for introducing fluids into reservoir 64 through a fluid inlet 78 formed in cover 68 (Figure 6). As mass 70 is heated, it will controllably expand from the

configuration shown in Figure 2 to the expanded configuration shown in Figure 3.

With the construction of the fluid storage device 52 shown in Figure 2, when the heat expandable mass 70 is heated it will tend to expand into the configuration shown in Figure 3 thereby forcing the fluid "F" contained within the reservoir 64 outwardly thereof through an outlet passageway 66. As mass 70 expands, it will also distend sealing membrane 72 as well as distendable membrane 74 in a direction toward inner wall 68a (Figure 2). It is to be noted that as membrane 74 moves toward its distended configuration, it will closely conform to the shape of heat-expandable mass 70 resulting in a complete and controlled expelling of fluid from reservoir 64 through fluid outlet 66 and into the infusion means 54 of the apparatus, the details of which will presently be described. It is to be understood that in certain embodiments of the invention only a single sealing membrane need be used to separate mass 70 from reservoir 64.

As best seen in Figure 2, cover 68, in cooperation with distendable membrane 74 forms reservoir 64. Medicament and instruction labels 69 (Figure 1) can be affixed to cover 68 to identify the medicinal fluid contained within reservoir 64 of the device.

For a discussion of the various materials that can be used to construct base 56, cover 68, and membranes 72 and 74, reference should be made to U. S. Patent No. 5,205,820. This patent also discusses in greater detail techniques for labeling and venting of the fluid storage device where necessary.

Forming a unique aspect of the apparatus of the present invention is the previously identified infusion means 54 for infusing medicinal fluids from fluid reservoir 64 into the patient. As best seen in figures 1 and 7, the infusion means here comprises the subcutaneous infusion device 83 which includes a base 84 having upper and lower surfaces 84a and 84b and

a generally circular-shaped opening 86 (Figure 7). Connected to the upper surface 84a of base 84 is the cover 88 having a generally dome-shaped portion 88a, a flange portion 88b, and a stem portion 88c (Figure 1). Removably receivable within opening 86 is a generally dome-shaped closure assembly 90 which includes an outer wall 92 which terminates in a generally cylindrically shaped skirt portion 92a. Formed in internally of wall 92 is a tubular-shaped, socket-like portion 94 (Figure 7), the purpose of which will presently be described.

Cover 88 and wall 92 cooperate to define a chamber 95 which houses the novel hollow cannula 100 of the invention. Cannula 100 includes a circuitously shaped body portion 100a which is disposed within chamber 95 and a stem portion 100b which is mounted within stem portion 88c of cover 88. Cannula 100 also includes an outlet end here provided in the form of a needle-like segment 100c which extends generally perpendicularly downward from surface 84b of base 84 and is used for subdermal infusion of medicinal fluids into the patient. For this purpose, segment 100c is provided with a sharp ground needle pointed extremity 100d (Figure 7). Also shown in Figure 7 is a twist-off protective sheath 102 which is telescopically received within socket-like portion 94 and surrounds and protects segment 100c of the cannula.

Preferably stem portion 100b of the very small diameter spiral cannula 100 is encased within the inboard end 108a of a fluid delivery administration tube 108 (Figure 1) and the assembly thus formed is rigidly supported within stem 88c by encapsulation means such as a standard potting compound 110 of a character well known to those skilled in the art. Compound 110 rigidly supports the stem portion of the cannula within stem 88c so as to provide a secure interconnection of the cannula with base 84 and cover 88.

As best seen in Figures 1, 4, and 6a, a quick connect assembly 112 enables quick



interconnection of the delivery administration tube or line 108 with cover 68 so that the delivery line is placed in fluid communication with outlet 66. Quick connect assembly 112 includes a body portion 114 having a hub 114a which is closely received within a socket 116 formed in cover 68 (Figure 1). Formed on hub 114a is an enlarged diameter, bead-like protuberance 115 which sealably engages socket 116. A locking flange 118 is provided proximate hub 114 and is adapted to be lockably engaged by a pair of resiliently deformable locking arms 120 provided on cover 68. A pair of finger engaging locking levers 122, which are connected to body portion 114, can be squeezed together in a manner to spread the arms apart a distance sufficient to permit the removal of flange 118 from between the hook-like extremities 120a of arms 120. As indicated in Figure 1, hook-like extremities 120a lockably grip flange 118 when socket portion 114 of the quick connect coupler is seated within cavity 116 provided in housing 68 of the device. However, when it is desired to separate the infusion set 54 from the storage device 52, an inward finger pressure exerted on arms 122 will spread extremities 120a a distance sufficient to permit passage of flange 118 and removal of hub 114a from cavity 116.

In using the apparatus of the present invention, reservoir 64 is first filled with the beneficial agent to be infused into the patient using the fill means of the invention. This fill means here comprises a non-coring, elastomeric septum 126, which as shown in Figure 6, is held in position within cover 68 by a clamping ring 128. Septum 126 is of standard construction and is penetrable by a cannula "C" of a filling syringe of conventional construction. The conventional syringe (not shown) can be used to introduce fluid to be dispensed into inlet passageway 78 and thence into reservoir 64. It is to be understood, however, that reservoir 64 can also be filled at the factory at the time of manufacture of the

fluid storage device. Alternatively, the reservoir can be filled in the field shortly before use by means of a conventional syringe of a character well known to those skilled in the art.

With reservoir 64 filled in the manner shown in Figure 2 of the drawings, the infusion device can be interconnected with the fluid storage device 52 in the manner previously described. This done, closure assembly 90 of the infusion device 54 is then separated from the base 84 and protective sheath 102 is slipped from end 100c of cannula 100. With end 100c of cannula 100 thus exposed, the infusion device can be interconnected with the patient by penetrating the patient's skin with the sharp point 100d of the infusion cannula 100. As the infusion needle penetrates the patient's skin and tissue, the lower surface of base 84, which is preferably coated with an adhesive "A" will engage the patient's skin so as to hold the device securely in position. If desired, a peelable cover can be emplaced over a portion of the lower surface of the device to maintain the adhesive "A" in a sterile condition until time of use.

When the fluid storage device 52 is affixed to the patient's body, such as to an arm, leg, or abdomen, the patient's body temperature acting through heat sink 56 will cause heat expandable poly\_\_\_\_\_ mass 70 to expand thereby causing the fluid "F" contained within reservoir 64 to controllably flow under pressure toward outlet passageway 66. For this purpose, mass 70 should controllably expand within a temperature range of between about 70 to 100 degrees Fahrenheit. The fluid "F" entering outlet passageway 66 will flow through a fluid flow control means, shown here as flow control assembly 67, into delivery tube 108 and then into inlet 100e of cannula 100 (Figure 7). Flow control assembly 67 is of a character well known to those skilled in the art and may comprise a rate control or impedance member 67a constructed from a porous ceramic, a plastic, a sintered metal or other suitable materials which will control the rate of fluid flow toward delivery tube 108. Also comprising a part of the flow

control means is a filter 67b for filtering particulate materials from the fluid flowing outwardly of the device.

An extremely important aspect of the invention relates to the novel design of the circuitously shaped cannula and its unique interconnection with base 84 and cover 88. With the novel construction shown in the drawings, when the device is connected to the patient so that the needle portion 100c of the cannula penetrates the patient's skin and tissue as, for example, is found on the patient's arm, leg, or abdomen, normal movement by the patient will permit the cannula to move within chamber 95 while the base remains completely stationary. Without this important feature, normal movements by the patient causing flexing of the muscle or tissue can cause irritation and discomfort to the patient and can possibly cause needle related tissue necrosis. However, the novel dynamic mounting of the cannula within chamber 95 positively prevents irritation to the patient as a result of normal muscle flexing by the patient.

Turning to Figures 8 through 12, an alternate form of the apparatus of the invention for use in the infusion of medicinal fluids into a patient is there shown and generally designated by the numeral 130. This alternate embodiment is similar in many respects to that shown in Figures 1 through 7 and like numerals are used in Figures 8 through 12 to identify like components. As best seen by referring to Figures 8 and 9, the apparatus here comprises a low-profile, fluid-storage device 132 and a cooperating infusion means 54 for infusing the fluid stored in device 132 into the patient. Infusion means 54 is identical to that previously described in connection with Figures 1 through 7. However, fluid storage device 132 is of a somewhat different construction. Fluid storage device 132 here comprises a thin base 136 having a central portion 136a and peripheral portion 136b circumscribing central portion 136a. Unlike base 56 of the earlier described embodiment, base 136 is provided with a curved lower

surface 136c of the character shown in Figure 9. Surface 136c is disposed proximate the patient when the device is taped or otherwise removably affixed to the patient, such as by using a foam tape 138 which has an adhesive "A" on both sides of the tape.

Formed within base 136 is a generally circular shaped chamber 140 within which a heat-expandable means is carried. As before, this heat-expandable means functions to controllably force the fluids contained within the sealed reservoir 144 of the device to flow outwardly through an outlet 146 formed in a cover 148 which is superimposed over base 136 in the manner shown in Figures 9, 10, and 11. The heat-expandable means is of the character previously described herein and is covered by a sealing means comprising a membrane 72 which is sealably connected to the peripheral portion 136b of base 136 in the manner indicated in Figures 9 and 12. Overlaying membrane 72 is a distendable barrier membrane 74 which is bonded to the cover and which, in cooperation with a cavity 148a formed in cover 148, forms fluid reservoir 144 (Figure 9). Fill means of the same character described in connection with the first embodiment of the invention are provided for introducing fluids into reservoir 144 through a fluid inlet 150 formed in cover 148. As the heat expandable means or semi-solid mass 70 is heated by the body heat of the patient, it will controllably expand causing any fluid contained within the reservoir to flow outwardly thereof through outlet passageway 146. As before, when mass 70 expands, it will distend sealing membrane 72 and distendable membrane 74 in a direction toward inner wall 148a of cavity 144a (Figure 9). It is to be noted that as membrane 74 moves toward its distended configuration, it will closely conform to the shape of heat-expandable mass 70 resulting in a complete and controlled expelling of fluid from reservoir 144 through fluid outlet passageway 146 and into the infusion means 54 of the apparatus.

As shown in Figure 8, a novel aspect of the apparatus of this latter form of the invention is the previously discussed infusion means or assembly 54. Assembly 54, which comprises a subcutaneous infusion device is of identical construction to that previously described and functions in an identical manner.

As best seen in Figures 8 and 10, a quick connect assembly 152 of a slightly different construction from quick connect assembly 112 is provided. Assembly 154, enables quick interconnection of the infusion means and delivery tube 108 with cover 148 so that the delivery tube or administration line is placed in fluid communication with outlet fluid passageway 146. Quick connect assembly 152 includes a body portion 154 having a hub 154a which is closely received within an elastomeric sleeve 155 carried within cover 148. Body portion 154 also includes an enlarged diameter flange 154b. Sleeve 155 is preferably formed of a co-molded elastomer which acts as a seal. Hub 154a is provided with an enlarged diameter bead-like protuberance 154c which sealably engages sleeve 155 to form a fluid tight seal. A locking member 156 functions to releasably maintain hub 154a seated within sleeve 155. Member 156 includes a centrally disposed, inwardly extending finger 158 (Figure 10), which is connected to, or integrally formed with, cover 148 in the manner shown in Figure 10, to form a living hinge type construction. Formed proximate the inboard end 156a of locking member 156 is a locking collar 160 which lockably engages flange 154b of assembly 154. Provided proximate the opposite or outboard end 156b of the locking member is an inwardly extending actuating arm 162. When an inward force is directed against arm 162, the locking member will pivot about finger 158 causing locking collar 160 to swing away from assembly 154 a sufficient distance to permit withdrawal of hub 154a from sleeve 155.

In using the apparatus of this latest form of the invention, reservoir 144 is filled with

the beneficial agent to be infused into the patient using the fill means of the invention. This fill means is of a similar construction to that described in connection with the embodiment of Figures 1 through 7 and includes an elastomeric asepticum 126 which comprises a non-coatable material and which is held in position within cover 148 by a plastic septum cover 166 which is bonded to cover 148. As before, septum 126 is of standard construction and is penetrable by a cannula of a conventional type syringe which can be used to introduce into inlet passageway 150 and thence into reservoir 144 the beneficial agent or medicinal fluid which is to be infused into the patient.

With reservoir 144 filled in the manner described, the infusion device is next interconnected with the fluid storage device 132 through appropriate manipulation of the locking member 156. This done, the infusion device can be interconnected with the patient in the same manner as previously described. As before, when the fluid storage device 132 is affixed to the patient's body, the patient's body temperature will cause heat expandable mass 70 to expand causing the fluid contained within reservoir 144 to controllably flow under pressure toward outlet passageway 146. The fluid will then flow through a flow control means, which is housed within sleeve 155. As best seen in Figure 9, sleeve 155 is sealably disposed within a bore 157 formed in cover 148. The flow control means is of the character previously described and comprises a porous rate control member 67a and a filter 67b both of which are housed within sleeve 155 and are in communication with delivery tube 108. With this construction, fluid flowing into outlet passageway 146 will flow through rate control assembly 67, into delivery tube 108 and then into the inlet of cannula 100. As before, rate control member 67a which is of the character previously described functions to regulate the rate of fluid flow toward delivery tube 108.

Referring next to Figures 13 through 15, still another form of the apparatus of the invention is there shown and generally designated by the numeral 170. This alternate embodiment is quite similar to that shown in Figures 8 through 12 and like numerals are used in Figures 13 through 15 to identify like components. As best seen by referring to Figures 13 and 14, the apparatus here comprises a low-profile, fluid-storage device 172 and a cooperating infusion means 54 for infusing the fluid stored in device 172 into the patient. Infusion means 54 is identical to that previously described in connection with Figures 1 through 7. However, fluid storage device 172 is of a slightly different construction in that it is designed to mate with a quick coupling mechanism of a somewhat different type.

Fluid storage device 172 here comprises a thin base 174 having a central portion 174a and peripheral portion 174b circumscribing central portion 174a. As before, base 174 is provided with a curved lower surface 174c of the character shown in Figures 9 and 14. As before, surface 174c is disposed proximate the patient when the device is taped or otherwise removably affixed to the patient, such as by using a foam adhesive tape 175 which has an adhesive "A" provided on both sides of the tape. Where appropriate peelable release liner can be provided over the lower surface of tape 175.

Formed within base 174 is a generally circular shaped opening 176 which receives a heat-expandable means of the character shown in Figure 14. As before, this heat-expandable means functions to controllably force the fluids contained within the sealed reservoir 180 of the device (Figure 14) to flow outwardly through an outlet passageway 182 formed in a cover 184 which is superimposed over base 174 in the manner shown in Figures 13 and 14. The heat-expandable means is of the character previously described herein and is held in position within opening 176 by a floor-like member 186 which is insert molded to base 174. Member

186 is preferably constructed of a metal such as aluminum or stainless steel which can be stamped into the required configuration so as to act as an effective heat sink. The heat expandable means or mass is covered by a sealing means comprising a membrane 72 which is sealably connected to the peripheral portion 174b of base 174 by any suitable means such as thermal bonding in the manner indicated in Figure 14. Overlaying membrane 72 and bonded to the cover by any suitable means is a distendable membrane 74 which, in cooperation with a generally concave-shaped cavity 184a formed in cover 184, forms fluid reservoir 180 (Figure 14). Fill means of the same character described in connection with the earlier embodiments of the invention is provided for introducing fluids into reservoir 180 through a fluid inlet passageway 188 formed in cover 184. As the heat expandable means or mass 70 is heated by the body heat of the patient, it will controllably expand causing any fluid contained within the reservoir to flow outwardly thereof through outlet passageway 182. As before, when mass 70 expands, it will distend sealing membrane 72 and distendable membrane 74 in a direction toward inner wall 184a of cavity 180 (Figure 14). It is to be noted that as membranes 72 and 74 move toward their distended configuration, they will closely conform to the resulting geometry of heat-expandable mass 70 resulting in a complete and controlled expelling of fluid from reservoir 180 through fluid outlet passageway 182 and into the infusion means 54 of the apparatus which is identical to that previously described.

As best seen in Figure 13, a quick connect assembly 190 of a somewhat similar construction to quick connect assembly 112 is provided. Assembly 190, enables quick interconnection of the infusion means and administration line 108 with cover 184 so that the line is placed in fluid communication with outlet passageway 182. Quick connect assembly 190 includes a body portion 192 having an inboard end 192a which is closely received within a



tubular member 194 which is co-molded within a bore 195 formed in cover 184 (Figures 13 and 14). Formed in cover 184 are a pair of spaced apart locking notches 196 which are adapted to be lockably engaged by a pair of resiliently deformable locking arms 198 which are attached to body portion 192. Arms 198 include a pair of finger engaging extremities 198a which can be squeezed together in a manner to spread the inboard ends of locking arms 198 apart a distance sufficient to permit the hook-like extremities 198b formed on arms 198 from notches 196. As indicated in Figure 13, hook-like extremities 198b lockably grip notches 196 when inboard end 192 of body 190 of the quick connect coupler is seated within tubular member 194. However, when it is desired to separate the infusion set 54 from the storage device 172, an inward finger pressure exerted on arm portions 198a will spread hook-like extremities 198b a distance sufficient to permit removal of portion 192 from tubular member 194.

In using the apparatus of the present form of the invention, reservoir 180 is first filled with the beneficial agent to be infused into the patient using the fill means of the invention. As before, the fill means here comprises an elastomeric septum 126, which as shown in Figure 14, is held in position within cover 184 by a clamping ring 128. Septum 126 is of standard construction and is penetrable by a cannula "C" of a syringe of conventional construction. The conventional syringe (not shown) can be used to introduce fluid to be dispensed into inlet passageway 188 and thence into reservoir 180.

With reservoir 180 filled, either at the manufacturer, or in the manner described in the preceding paragraph, the infusion device can be interconnected with the fluid storage device 172 in the manner previously described. This done, closure assembly 90 of the infusion device 54 (Figure 7) is then separated from the base 84 and protective sheath 102 is slipped from end 100c of cannula 100. With end 100c of cannula 100 thus exposed, the infusion device can be

interconnected with the patient by penetrating the patient's skin with the sharp point 100d of the infusion cannula 100. As the infusion needle penetrates the patient's skin and tissue, the lower surface of base 84 (Figure 7) which is coated with an adhesive "A" will engage the patient's skin so as to hold the device securely in position.

When the fluid storage device 172 is affixed to the patient's body, such as to an arm, leg, or abdomen the patient's body temperature will cause heat expandable mass 70 to expand thereby causing the fluid contained within reservoir 180 to controllably flow under pressure toward outlet passageway 182. The fluid entering outlet passageway 182 will flow through a fluid flow control means, shown here as the previously described porous rate control member 67, into delivery tube 108 and then into inlet 100e of cannula 100 (Figure 13).

Turning next to Figures 16 through 18, another embodiment of the invention is there shown and generally designated by the numeral 200. This alternate embodiment is similar in many respects to that shown in Figures 13 through 15 and like numerals are used in Figures 16 through 18 to identify like components. As shown in Figures 16 and 17, the apparatus once again comprises a low-profile, ambulator fluid-storage device 202 and a cooperating infusion means 54 for infusing the fluid stored in device 202 into the patient. Infusion means 54 is identical to that previously described in connection with Figures 1 through 7. The fluid storage device 202, on the other hand, is of a slightly different construction in that it includes a differently configured membrane 205 which overlays the heat expandable means of the invention. The fluid storage device 202 is also designed to mate with a quick coupling mechanism of a somewhat different type. Fluid storage device 202 here comprises a thin base 204 having a central portion 204a and peripheral portion 204b circumscribing central portion 204a. As before, base 204 is provided with a curved lower surface 204c of the character

shown in Figures 17 and 18. As before, the lower peripheral portion of the base is disposed proximate the patient when the device is taped or otherwise removably affixed to the patient, such as by using a double sided adhesive foam tape.

Formed within base 204 is a generally circular shaped opening 206 which receives a heat-expandable means of the character previously described herein. Once again, this heat-expandable means functions to controllably force the fluids "F" contained within the sealed reservoir 208 of the device (Figure 17) to flow outwardly through an outlet passageway 210 formed in a cover 214 which is superimposed over and connected to base 204 in the manner shown in Figures 17 and 18. The heat-expandable means or mass 70 is held in position within opening 206 by floor-like member 209 which is connected to base 204. Member 209 is preferably constructed of metal such as aluminum, stainless steel or the like and functions as a heat sink. The heat expandable means or mass 70 is covered by a specially configured sealing means which comprises a distendable membrane 205. Membrane 205 includes a peripheral sealing flange 205a which is sealably received within grooves 217 formed in the peripheral portions of member 209 and cover 214 in the manner indicated in Figure 17. As best seen in Figure 18, flange or bead 205a is generally circular in cross-section while grooves 217 also cooperate to form a peripheral cavity which is also generally circular in cross-section. Bead 205a is preferably slightly larger than its receiving cavity so that, when held in compression, a substantially leak-proof seal is formed when cover 214 is bonded with base 204 in the manner shown in Figure 17.

Overlaying membrane 205 is a distendable drug barrier membrane 74 which, in cooperation with a cavity 214a formed in cover 214, forms fluid reservoir 220 (Figure 17). Fill means of the same character described in connection with the earlier embodiments of the

invention is provided for introducing fluids into reservoir 220 through a fluid inlet passageway 222 formed in cover 214. As the heat expandable means or mass 70 is heated by the body heat of the patient via heat sink member 209, it will controllably expand causing any fluid contained within the reservoir to flow outwardly thereof through outlet passageway 210. As before, when mass 70 expands, it will distend sealing membrane 205 and distendable membrane 74 in a direction toward inner wall 214b of cavity 214a. It is to be noted that as membranes 205 and 74 move toward their distended configuration, they will closely conform to the shape of heat-expandable mass 70 resulting in a complete and controlled expelling of fluid from reservoir 220 through fluid outlet passageway 210 and into the infusion means 54 of the apparatus via the flow control means.

Operably coupled with device 202 is the previously discussed infusion means or assembly 54. Assembly 54, which comprises a subcutaneous infusion device is of identical construction to that previously described and functions in an identical manner.

As best seen in Figure 16, a quick connect assembly 225 enables quick interconnection of the infusion means and delivery tube 108 with cover 214 so that the delivery tube is placed in fluid communication with outlet passageway 210 and the flow control means. Quick connect assembly 225 includes a body portion 227 having an inboard end 227a which is closely received within a stepped bore 230 formed in cover 214 (Figures 16 and 17). Formed on cover 214 is a locking gate 232 (Figure 16) which is adapted to lockably engage a resiliently deformable locking arm 234 which is attached to body portion 227. Arm 234 can be urged inwardly toward body portion 227 a distance sufficient to permit the extremity of arm 234 to snap free of the locking gate to permit removal of portion 227a from stepped bore 230. Locking gate 232 and arm 234 are of a conventional construction well understood by those

skilled in the art.

In using the apparatus of this form of the invention, reservoir 220 is first filled with the beneficial agent to be infused into the patient using the fill means of the invention. As before, the fill means here comprises an elastomeric septum 126, which, as shown in Figure 17, is held in position within cover 214 by a sonic crush bonded ring 128. Septum 126 is of standard construction and is penetrable by a cannula "C" of a syringe of conventional construction. The conventional syringe (not shown) can be used to introduce fluid to be dispensed into inlet passageway 222 and thence into reservoir 220.

With reservoir 220 filled either at the manufacturer or in the manner described in the preceding paragraph, the infusion device can be interconnected with the fluid storage device 202 in the manner previously described. This done, the infusion device 54 can be interconnected with the patient in the same manner as previously described herein.

As before, when the fluid storage device 202 is affixed to the patient's body, the patient's body temperature will cause heat expandable mass 70 to expand thereby causing the fluid contained within reservoir 220 to controllably flow under pressure toward outlet passageway 210. The fluid entering outlet passageway 210 will flow through a fluid flow control means, shown here as the previously described filter 67b and porous rate control member 67a, into delivery tube 108 and then into inlet 100e of cannula 100 (Figure 16).

Referring next to Figures 19 through 24, yet another form of the apparatus of the invention is there shown. This alternate form of the invention is somewhat similar to that shown in Figures 13 through 15 and like numerals are used in Figures 19 through 21 to identify like components. As best seen by referring to Figures 19, 20, and 21, the apparatus here comprises a low-profile, fluid-storage device 242 (Figure 19) and a cooperating infusion

means 54 (Figure 21) for infusing the fluid stored in device 242 into the patient. Infusion means 54 is identical to that previously described. However, fluid storage device 242 is of a slightly different construction in that it is designed to mate with a single lever arm type quick coupling mechanism 243 (Figure 19).

Fluid storage device 242 here comprises a thin base 244 having a central portion 244a and peripheral portion 244b circumscribing central portion 244a. Base 244 is provided with a lower surface 244c of the character shown in Figures 20 and 21. As before, surface 244c is disposed proximate the patient when the device is taped or otherwise removably affixed to the patient, such as by using a pad 245 which may have an adhesive provided on both sides of the pad.

Formed within base 244 is a generally circular shaped cavity 246 which receives a heat-expandable means which, as before, functions to controllably force the fluids contained within the sealed reservoir 248 of the device (Figure 20) to flow outwardly through an outlet 250 formed in a cover 252 which is superimposed over base 244 in the manner shown in Figures 20 and 23. The heat-expandable means is of the character previously described herein and is held in position within cavity 246 by a membrane 72 which is sealably connected to the peripheral portion 244b of base 244 in the manner indicated in Figure 20. Overlaying membrane 72, which is of the character previously described, is a distensible membrane 74 which, in cooperation with a generally concave shaped cavity 252a (Figure 22) formed in cover 252, forms fluid reservoir 248 (Figure 20). Fill means of the same character described in connection with the earlier embodiments of the invention is provided for introducing fluids into reservoir 248 through a fluid inlet 254 formed in cover 252 (Figures 19 and 23). As the heat expandable means or mass 70 is heated by the body heat of

the patient, it will controllably expand causing any fluid contained within the reservoir to flow outwardly thereof through outlet passageway 250. As before, when mass 70 expands, it will distend sealing membrane 72 and distendable membrane 74 in a direction toward inner wall 252b of cavity 252a (Figure 22). It is to be noted that as membranes 72 and 74 move toward their distended configuration, they will closely conform to the shape of heat-expandable mass 70 resulting in a complete and controlled expelling of fluid from reservoir 248 through fluid outlet 250 and into the infusion means 54 of the apparatus.

As shown in Figure 20, cover 252 in cooperation with distendable membrane 74 forms reservoir 248. Cover 252 may be constructed of various materials such as polypropylene, polyvinylidene, styrene and the like. Similarly, base 244 can be constructed from various metals and plastics. If desired, medicament and instruction labels can be affixed to the cover 252 to identify the medicinal fluid contained within reservoir of the device.

As before, the infusion means or assembly 54 comprises a subcutaneous infusion device which is of identical construction and operation to that previously described and functions in an identical manner. Assembly 54 uniquely interconnected with fluid storage device 242 by means of the quick connect mechanism 243 which is somewhat similar to quick connect assembly 190. Here mechanism 243 includes a body portion 259 having an inboard end 259a which is closely received within an elastomeric glove 260 which is mounted within bore 262 formed in cover 252 (Figure 23). End 259a includes a pronuberance 259b which sealably engages sleeve 260 to form a fluid tight seal. Formed in cover 252 is a locking notch 264 which is adapted to be lockably engaged by a resiliently deformable locking arm 266 which is attached to body portion 259 by a living hinge connection 267. Arm 266 includes a finger engaging extremity 266a which can be urged inwardly toward body 259 in a manner to

separate the inboard end of locking arm 266 from notch 264 by a distance sufficient to permit the hook-like extremity 266b formed on arm 266 to be separated by notch 264 so as to enable separation of the infusion set 54 from the storage device 242.

The method of use of the apparatus of this latest form of the invention, is quite similar to that defined in connection with the earlier described embodiments, and therefore will not be discussed further at this time.

Suffice to say that after the reservoir 248 is filled and the fluid delivery device 242 is operably connected to the infusion set 54, the fluid storage device 242 is affixed to the patient's body, in a manner such that the patient's body temperature will cause heat expandable mass 70 to expand thereby causing the fluid contained within reservoir 248 to controllably flow under pressure toward outlet 250, through the previously described porous rate control member 67 and into delivery tube 108. The fluid will then flow into inlet 100e of cannula 100 for delivery to the patient (Figure 21).

Referring now to Figures 25 through 28, a quite different form of the apparatus of the invention for use in the infusion of medicinal fluids into a patient is there shown. As best seen by referring to Figures 25 and 26, this latest form of the invention comprises a low-profile, fluid delivery device 270 which incorporates as a part of the device an integral, rather than a separate, remotely disposed infusion means for infusing the fluid stored in the device into the patient.

More particularly, as shown in Figures 26 and 27, fluid delivery device 270 includes a thin base assembly 272 having an upper surface 272a including a central portion 273 and peripheral portion 275 circumscribing central portion 273. Base 272 is also provided with a lower surface 272b which is located proximate the patient when the device is taped or



otherwise removably affixed to the patient such as by a pad 278 having an adhesive on both sides of the pad.

Formed within base assembly 272 is a cannula receiving channel 280 (Figures 25 and 28) within which the body portion of a novel spiral-like hollow cannula or capillary 282 is uniquely mounted in a manner presently to be described. Base 272 also has a central, generally U-shaped cavity 284 formed in its upper surface 272a which closely receives a specially shaped, heat-expandable means which functions to controllably expel the fluids contained within the sealed reservoir 286 of the device (Figure 25). When the expandable means is heated by the body temperature of the patient, it will controllably expand and cause the medicinal fluid contained within the reservoir to flow outwardly through an outlet 288 formed in the cover 290 which is superimposed over base 272 (see Figures 26 and 28).

The heat expandable means is here provided in the form of a generally U-shaped temperature expandable member 292 which is disposed within cavity 284 in the manner best illustrated in Figure 28. Superimposed over cavity 284 and expandable member 292 is a sealing means for sealing cavity 284. This sealing means here comprises an elastomeric membrane 289 which is sealably connected to a strategically shaped floor 295 which forms a part of base assembly 272. Floor 295 which is preferably provided in the form of a metal stamping, is connected to an upper base member 297 which also forms a part of base assembly 272. With this construction, and for reasons presently to be described, floor 295 functions as an efficient heat sink. Overlaying membrane 289 is a distendable membrane 299 which, in cooperation with a generally concave shaped surface 290a formed on cover 290, forms the fluid reservoir 280 (Figure 25). In a manner presently to be described, fill means are provided for introducing fluids into reservoir 280 through a fluid inlet 300 formed in cover 290 (Figures

25, 26 and 27). As member 292 is heated by the patient's body, it will controllably expand from the normal, relaxed configuration shown in Figure 27 to the expanded configuration shown in Figure 26. As heat expandable member 292 expands into the configuration shown in Figure 26; it will distend sealing membrane 289 as well as distendable membrane 299 in a direction toward concave inner wall 290a of cover 290 (Figure 26) and will cause the fluid contained within the fluid reservoir to flow outwardly through outlet 288. It is to be noted that as membrane 299 moves toward its distended configuration, it will closely conform to the shape of heat-expandable member 292 resulting in a complete and controlled expelling of fluid from reservoir 286 outwardly of the device through fluid outlet 288 and then into the infusion means, or cannula 282.

Once again, for a discussion of the various materials that can be used to construct base 56, cover 68, and membranes 72 and 74, reference should be made to U. S. Patent No. 5,205,820 and to Application Serial No. 08/541,030. These disclosures also discuss in greater detail techniques for labeling and venting of the fluid delivery device. Forming a unique aspect of the apparatus of the present invention is the novel infusion means of this latest form of the invention for infusing medicinal fluids from fluid reservoir 286 into the patient. As shown in the drawings, the infusion means here forms an integral part of the fluid delivery device and is in direct communication with outlet 288.

More particularly, the infusion means here comprises the previously identified circuitously shaped hollow cannula 282 as well as flow control means for controlling fluid flow into cannula 282. As best seen in Figure 28, cannula 282 includes a piercing extremity 282a and a body portion 282b which is mounted within channel 280 in a novel manner presently to be described. The flow control means, which includes rate control means and cooperating

filter means, here includes a porous rate control member 304 and a porous filter 306. As indicated in Figures 26 and 27, the flow control means is disposed between the outlet 288 of reservoir 286 and an inlet passageway formed 307 formed in the periphery of base 272.

Cannula 282 includes an inlet end 282c which communicates with passageway 307 and also includes the previously mentioned outlet end 282a, which comprises a needle-like segment that extends generally perpendicularly downward from the lower surface of heat sink plate, or floor 295 for subdermal infusion of medicinal fluids into the patient. For this purpose, outlet end 282a is provided with a sharp, pointed extremity. To maintain the outlet end in a sterile condition, a protective sheath 310 is provided. Sheath 310 surrounds the outwardly extending cannula segment and is removably affixed to floor 295 in the manner shown in Figure 26.

Filling of reservoir 286 is accomplished in the manner previously described by introducing fluid into the reservoir under pressure via a septum assembly 312 mounted in cover 290 (Figures 26 and 27). Septum assembly 312 includes a conventional elastomeric septum 312a and a deformable retaining ring 312b, both of which are of the general character previously described. During this fill step, the space between the upper surface of membrane 299 and the concave surface 290a of cover 290 is substantially filled with the fluid to be infused into the patient.

With this construction, when the fluid is dispensed from the device as a result of the heating of expandable member 292, the member 292 will function as a conformable ullage which, in cooperation with the distendable member 299 will provide a constant fluid expelling pressure on the fluid contained within the reservoir throughout the fluid delivery cycle, thereby avoiding undesirable delivery rate tail off at the end of the delivery period. This novel, substantially linear performance of the device enables it to meet even the most stringent

medicinal fluid delivery requirements.

As best seen in Figure 26, during the fluid delivery step, fluid will flow from reservoir 286 into passageway 288. A plug 312 provided in the outboard end of passageway directs fluid flow through the flow control means in the direction of the arrow of Figure 26 and then into inlet end 282c of cannula 282. The flow control means can be constructed from various porous materials including those described in Serial No. 08/541,030 which is incorporated herein by reference. After flowing through the flow control means, the fluid will flow outwardly of the device via the hollow cannula 282.

Turning once again to Figure 28, it is to be observed that part of the body portion 282b of spiral cannula 282 is uniquely supported within channel 280 of base assembly 272 by a cannula encapsulation means shown here as a standard potting compound "P". Compound "P" rigidly supports the body portion of the cannula within channel 280 and dynamically supports the outer extremity of the cannula body so that a spring-like portion 282d of the cannula is free to move three dimensionally within a hollow chamber 314 provided in the base assembly (Figure 28). With this highly novel construction, then the device is connected to the patient using adhesive coated pad 278 and with the needle portion 282a of the cannula penetrating the patient's body, as, for example, the patient's arm or leg, normal movement by the patient will permit the cannula to move within a portion of chamber 314 while the base components 295 and 297 remain completely stationary. Without this important feature, normal movements by the patient causing flexing of the muscle and tissue would impart loosening forces to the device which in time, could cause the adhesive pad 278, provided on the floor component 295 of the base to separate from the patient's skin. This important feature of the invention is discussed more fully in Applicant Serial No. 08/541,030 as are

various other optional configurations of the spiral cannula 282.

Turning next to Figures 29 through 38, still another embodiment of the apparatus of the invention for use in the infusion of medicinal fluids into a patient are there shown. This latest form of the invention also comprises a low-profile, fluid delivery device generally identified by the numeral 320 which incorporates an integral, infusion means for infusing the fluid stored in the device into the patient and also includes a novel fluid flow indicator means for indicating fluid flow from the device.

As illustrated in Figures 29, 30, 31, and 37, fluid delivery device 320 is of a substantially different configuration from the earlier described embodiment in that the heat expandable means is generally annular in shape. However, as before, the device includes a thin base assembly 322 having an upper surface 322a including a central portion 323 and peripheral portion 325 circumscribing central portion 322. Base 322 is also provided with a lower surface 322b which is located proximate the patient when the device is taped or otherwise removably affixed to the patient such as by a pad 328 having an adhesive "A" on at least the lower side of the pad.

Formed within base assembly 322 is a fluid delivery means receiving cavity 330 (Figures 31 and 32) within which the fluid delivery means of the invention for delivering medicinal fluids to the patient is received. Forming a part of the fluid delivery means is infusion means here shown as hollow cannula or capillary 332 which is mounted within cavity 330 in a manner presently to be described. Base assembly 322 also has a central, generally annular-shaped cavity 336 which closely receives the previously mentioned, generally annular-shaped, heat-expandable means which functions to controllably expel the fluids contained within the sealed reservoir 338 of the device (Figure 32). As will be discussed in

greater detail hereinafter, when the heat expandable means is heated by the patient's body, it will cause the medicinal fluids contained within reservoir 338 to flow outwardly through an outlet 340 formed in the cover 342 which is superimposed over base assembly 322 in the manner shown in Figures 31 and 36).

The heat expandable means, which is here provided in the form of a generally annular-shaped temperature expandable member 344, is disposed within cavity 336 in the manner best illustrated in Figure 36. Superimposed over cavity 336 and expandable member 344 is a sealing means for sealing cavity 336. This sealing means here comprises an elastomeric membrane 346 which is sealably connected to a generally circularly shaped floor 348 which forms a part of base assembly 322. Floor 348 circumscribes cavity 336 as well as fluid delivery means receiving cavity 320 in the manner shown in Figure 36. Overlaying membrane 346 and connected to cover 342 (Figure 33) is a second distendable membrane 350 which, in cooperation with a generally concave shaped surface 342a formed on cover 342, forms the fluid reservoir 338 (Figure 32). As in the earlier-described embodiments, fill means are provided for introducing fluids into reservoir 338 through a fluid inlet 352 formed in cover 342 (Figure 31). As member 344 is heated by the patient's body, it will controllably expand from the normal, relaxed configuration shown in Figures 31 and 32 into an expanded configuration. As heat expandable member 344 expands into the expanded configuration, it will distend sealing membrane 346 as well as distendable membrane 350 in a direction toward concave inner wall 342a of cover 342 and will cause the fluid contained within the fluid reservoir to flow outwardly through a reservoir outlet 356 (Figure 31). It is to be noted that reservoir outlet 356 is in communication with both passageways 340 and 352 and, therefore, acts both as an inlet and an outlet passageway. As before as membrane 350 moves toward its

distended configuration, it will closely conform to the shape of heat-expandable member 344 resulting in a complete and controlled expelling of fluid from reservoir 338. As fluid is forced from reservoir 338, it will flow into fluid outlet 356, then into passageway 340 and then into the infusion means, or cannula 332 via a passageway 358 formed in base assembly 322.

Passageway 358 is formed in a radially extending protuberance 358a formed on base assembly 322 (Figure 36) which protuberance extends through a gap 344a formed in expandable member 344. Once again, for a discussion of the various materials that can be used to construct base 322, cover 342, and membranes 346 and 350, reference should be made to U. S. Patent No. 5,205,820 and to Application Serial No. 08/541,030. These disclosures also discuss in greater detail techniques for labeling and venting of the fluid delivery device.

Forming a unique aspect of this latest embodiment of the invention is the previously mentioned fluid delivery means for delivering medicinal fluids from fluid reservoir 338 into the patient. More particularly, the fluid delivery means here comprises the previously identified hollow cannula 332 as well as flow control means for controlling fluid flow into cannula 332 (see Figure 38). As best seen in Figures 31 and 38, cannula 332 includes a piercing extremity 322a and an inboard inlet end 332b. The flow control means, which includes rate control means comprising a porous rate control member 362 to which cannula 332 is connected as by laser welding. As indicated in Figures 31 and 32, the rate control means is disposed proximate outlet passageway 358 formed in base assembly 322. Cannula 332, along with rate control member 362, is held securely in position within cavity 330 in a potting compound 363 or by any suitable adhesive. In the instant form of the invention, cannula 332 extends generally perpendicularly downward from base assembly 322 for subdermal infusion of medicinal fluids into the patient. For this purpose, piercing extremity or

outlet end 332a is provided with a sharp point and is maintained in a sterile condition by a tear away type protective sheath 366. As shown in figures 31, 36, and 37, sheath 366 surrounds the outwardly extending cannula and is removably affixed to a collar 366a which is connected to base assembly 322 in the manner shown in Figure 31.

A further novel aspect of the fluid delivery apparatus 320 of the invention is the provision of a flow indicator means for indicating fluid flow from reservoir 338 caused by the expansion of heat expandable member 344. This flow indicator means is here provided as a generally disk shaped indicator member 370 which is disposed within reservoir 338. As best seen in Figures 31 and 31A, a member 370 includes a first surface 370a, a second surface 370b defined by a first stepped section, a third surface 370c defined by a second stepped section and a fourth surface 370d defined by a third stepped section. First surface 370a is of a first color, such as green; third surface 370c is of a second color, such as yellow; and fourth surface 370d is of a third color, such as red. For reasons presently to be described, disk shaped indicator member 370 is preferably formed of a yieldably deformable material, such as a sponge.

Centrally disposed within cover 342 is a clear or smoked plastic window element 342b. When reservoir 338 is fitted, sponge indicator member is in a relaxed state as shown in Figure 31 and surface 370a is in engagement with window 342b so as to display green indication that the reservoir is filled. As heat distendable member 344 expands, indicator member will be compressed to a point at which surface 370c engages window 342b so as to display yellow indication that reservoir 338 is only partially full. Continued expansion of member 344 will cause compression of indicator member 370 to a point at which surface 370d engages window 342b showing red and indicating that reservoir 338 is empty.

Turning to Figures 31B and 31C, the same basic fluid delivery device as shown in



Figures 31 through 35 is there illustrated and like numerals are used to identify like components. However, in this embodiment, a slightly different fluid flow indicator means is provided. This means, which is provided as a yieldably deformable, sponge-like member 371, is similar in construction to indicator member 338 in a slightly different manner.

As before the flow indicator means comprises a generally disk-shaped member which is disposed within reservoir 338. As best seen in Figure 31B and 31C, member 371 includes a first surface 371a, a second surface 371b defined by a first stepped section, and a third surface 371c defined by a second stepped section, and a fourth surface 371d defined by a third stepped section. Second surface 371b is of a first color, such as red, third surface 371c is of a second color, such as yellow; and fourth surface 371d is of a third color such as green.

With the construction shown in Figures 31B and 31C, when reservoir 338 is filled, sponge indicator member 371 is in a relaxed state as shown in Figure 31B and surface 371d is engaged with window 342b so as to display green indication that the reservoir is filled. As heat distendable member 344 expands, indicator member will be compressed to a point at which surface 371c engages window 342b so as to display yellow indicating that reservoir 388 is only partially full. Continued expansion of member 344 will cause compression of indicator member 371 to a point at which surface 371b engages window 342b showing a red color and indicating that reservoir 338 is empty.

Turning to Figures 39 and 40, two alternate forms of fluid delivery means of the invention are shown. These fluid delivery means are similar in many respects to the fluid delivery means described in connection with Figures 29 through 38 and include a hollow delivery cannula for delivering fluid to the patient. However, in the fluid delivery means shown in Figure 39, the hollow cannula 375 is provided with a flared inboard end 375a which

communicates directly with the fluid reservoir of the device. More particularly, in this embodiment of the invention, the flow rate control member has been replaced with a stainless steel support collar 377 which is receivable within cavity 369 of the base assembly.

In the embodiment shown in Figure 40, the cannula 379 is similar in configuration to cannula 375 in that it has a flared inlet end 379a. However, in this instance cannula 379 is supported within a porous rate control member 381 which is similar in characteristics to rate control member 362.

Filling of reservoir 388 is accomplished in the manner previously described by introducing fluid into the reservoir under pressure via a filling means or septum assembly 372 which is mounted in cover 342 (Figures 31 and 36). Septum 372 includes a conventional elastomeric septum 372a and a deformable retaining ring 372b, both of which are of the general character previously described. During this fill step, the space between the upper surface of membrane 350 and the concave surface 342a of cover 342 is substantially filled with the fluid to be infused into the patient.

During the fluid delivery step, fluid will flow from reservoir 338 into passageway 356, into passageways 340 and 358 and then through the flow control means in a direction toward the inlet end 332b of cannula 332. After flowing through the flow control means, the fluid will flow outwardly of the device via the hollow cannula 332.

Referring next to Figures 41 through 42, still another form of the apparatus of the invention for use in the infusion of medicinal fluids into a patient is there shown and generally designated by the numeral 400. This alternate embodiment is similar in many respects to that shown in Figures 8 through 12 and like numerals are used in Figures 41 through 42 to identify like components. As shown in Figures 41 and 42, the apparatus here comprises a low-profile,

fluid-storage device 402 and a cooperating infusion means 404 for infusing the fluid stored in device 402 into the patient. Infusion means 404 is of substantially different construction to that previously described in connection with Figures 8 through 12. Similarly, fluid storage device 402 is also of a somewhat different construction.

Fluid storage device 402, as before, comprises a thin base 406 having a curved lower surface 406a which is disposed proximate the patient when the device is taped or otherwise removably affixed to the patient. Formed within base 406 is a generally circular shaped chamber 408 (Figure 42) within which the heat-expandable means is carried. This heat-expandable means is identical to that previously described and functions to controllably force the fluids contained within the sealed reservoir 410 of the device to flow outwardly through an outlet passageway 412 formed in a cover 414 which is superimposed over and connected to base 406 in the manner best seen in Figure 42. The heat-expandable means, or member 70 is covered by a sealing means which here comprises a single membrane 416 which is sealably connected to the peripheral portion of base 406 in the manner indicated in Figure 42. In this embodiment of the invention, membrane 426 comprises a distensible barrier membrane which take the place of the earlier described membranes 72 and 74. In cooperation with a surface 414a formed in cover 414, barrier membrane 426 forms the fluid reservoir 410 of the device. Fill means of the same character described in connection with the first embodiment of the invention are provided for introducing fluids into the reservoir 410, which is defined by surface 414a, through a fluid inlet 420 formed in cover 414. As the heat expandable means or semi-solid mass 70 is heated by the body heat of the patient, it will controllably expand causing any fluid contained within the reservoir to flow outwardly thereof through outlet passageway 412. When mass 70 expands, it will distend barrier membrane 416

in a direction toward surface 414a (Figure 42). As barrier membrane 416 moves toward its distended configuration, it will closely conform to the shape of heat-expandable mass 70 resulting in a complete and controlled expelling of fluid from reservoir 410 through fluid outlet passageway 412 and into the infusion means 404 of the apparatus.

As shown in Figure 46, a novel aspect of the apparatus of this latter form of the invention is the previously mentioned intravenous infusion means or assembly 404. Assembly 404 comprises an intravenous needle assembly 424 which includes a needle support 426 and a hollow needle 428 supported thereby. Connected to support 426 is a conventional butterfly assembly 430 for use in affixing the needle assembly to the patient. A breakaway needle cover 428a surrounds and protects needle 428. An elongated administration line 432 interconnects the needle assembly with the fluid delivery device and functions to place reservoir 410 in communication with hollow needle 428 via a flow control means and a stub outlet passageway 434 (Figure 42).

In using the apparatus of this latest form of the invention, reservoir 144 is filled with the beneficial agent to be infused into the patient using the fill means of the invention. This fill means is of a similar construction to that described in connection with the embodiment of Figures 1 through 7 and includes a septum 126 which comprises a non-corable material and which is held in position within cover 414 by a plastic septum cover 436 which is bonded to cover 414. As before, septum 126 is of standard construction and is penetrable by a cannula of a conventional type syringe which can be used to introduce fluid into inlet passageway 420 and thence into reservoir 414 the beneficial agent or medicinal fluid which is to be infused into the patient.

With reservoir 410 filled in the manner described, and with the infusion device

interconnected with the fluid storage device 402 in the manner shown in Figures 41 and 42, when the fluid storage device 402 is affixed to the patient's body, the patient's body temperature will cause heat expandable mass 70 to expand causing the fluid contained within reservoir 410 to controllably flow under pressure toward outlet passageway 412 through the flow control means and into stub passageway 434. The flow control means is of the character previously described and comprises a porous rate control member 440 and a filter 442 both of which are housed within a sleeve 444 disposed within a bore 445 formed in cover 414 and are in communication with delivery tube 108. With this construction, fluid flowing into outlet passageway 412 will flow through filter 442, through rate control assembly 440, into stub passageway 434, into administration line 432 and then into the inlet of hollow cannula 428.

Turning to Figures 43 through 47, yet another form of the apparatus of the invention for use in the infusion of medicinal fluids into a patient is there shown and generally designated by the numeral 450. This alternate embodiment is similar in many respects to that shown in Figures 41 through 42 and like numerals are used in Figures 43 through 47 to identify like components. As shown in Figures 41 and 42, the apparatus here comprises a low-profile, fluid-storage device which is substantially identical to fluid storage device 402 and a cooperating infusion means which is somewhat similar to infusion means 404. In this latest embodiment, the cannula portion of the infusion means rather than being remotely located, is integrally formed with the fluid storage device.

Fluid storage device 452, as before, comprises a thin base 454 having a curved lower surface 454a which is disposed proximate the patient when the device is taped or otherwise removably affixed to the patient. Formed within base 454 is a generally circular shaped chamber 456 within which the heat-expandable means is carried. This heat-expandable means

is identical to that previously described and functions to controllably force the fluids contained within the sealed reservoir 458 of the device to flow outwardly through an outlet passageway 460 formed in a cover 464 which is superimposed over and connected to base 460 in the manner best seen in Figure 42. The heat-expandable means, or member 70 is covered by a sealing means which here comprises a distended membrane 466 which is sealably connected to the peripheral portion of base 460 in the manner indicated in Figure 44. In this embodiment of the invention, second distendable membrane 468 overlays membrane 466 and is affixed to a cover 464. In cooperation with a surface 464a formed in cover 464, membrane 468 forms the fluid reservoir 458 of the device. Fill means of the same character described in connection with the first embodiment of the invention are provided for introducing fluids into the reservoir 458, which is defined by surface 414a, through a fluid inlet 472 formed in cover 464. As the heat expandable means or semi-solid mass 70 is heated by the body heat of the patient, it will controllably expand causing any fluid contained within the reservoir to flow outwardly thereof through outlet passageway 460. When mass 70 expands, it will distend membranes 466 and 468 in a direction toward surface 468a (Figure 42). As barrier membrane 466 moves toward its distended configuration, it will closely conform to the shape of heat-expandable mass 70 resulting in a complete and controlled expelling of fluid from reservoir 458 through fluid outlet passageway 460 and into the infusion means of the apparatus.

As shown in Figures 43 and 44, a novel aspect of the apparatus of this latter form of the invention is the previously mentioned intravenous infusion means, which is shown here as an infusion assembly 476. Assembly 476 comprises an intravenous needle assembly 480 which includes a needle support 482 and a hollow needle 484 supported thereby. As best seen in Figure 44, needle support 482 is connected directly to cover 470. Connected to support 482 is

a conventional butterfly assembly 430 of the character previously described for use in affixing the needle assembly to the patient. As indicated in the drawings, the elongated administration line shown in Figures 41 and 42 has been eliminated and support 482 functions to place reservoir 458 in communication with hollow needle 484 via a different type of flow control means, the character of which will presently be described.

In using the apparatus of this latest form of the invention, reservoir 458 is filled with the beneficial agent to be infused into the patient using the fill means of the invention. This fill means is of identical construction to that described in connection with the embodiment of Figures 41 through 42 and includes a septum 126 which comprises a non-corable material and which is held in position within cover 470 by a plastic septum cover 436 which is bonded to cover 470. As before, septum 126 is of standard construction and is penetrable by a cannula of a conventional type syringe which can be used to introduce fluid into inlet passageway 472 and thence into reservoir 458 the beneficial agent or medicinal fluid which is to be infused into the patient.

With reservoir 458 filled in the manner described, and with the fluid delivery device interconnected with the patient in a manner such that cannula 464 pierces the patient's vein. The patient's body temperature will cause heat expandable mass 70 to expand causing the fluid contained within reservoir 458 to controllably flow under pressure toward outlet passageway 460 through the flow control means and into passageway 482a of support 482. The flow control means of this latest form of the invention comprises a novel rate control member 487 which is housed within a bore 489 formed in cover 470 (Figures 44 and 45). As best seen in Figures 46 and 47 member 287 is provided with a microbore 491 which is in communication with fluid passageways 460 and 482a. With this construction, fluid flowing into outlet

passageway 460 will flow through microbore 491 or rate control member 487, into passageway 482a, and then into the inlet of hollow cannula 484. It is, of course, apparent that by carefully controlling the size of microbore 491, the rate of fluid flow toward the infusion means can be precisely controlled.

Turning finally to Figures 48 through 51, yet another form of the apparatus of the invention for use in the infusion of medicinal fluids into a patient is there shown and generally designated by the numeral 500. This alternate embodiment is similar in many respects to that shown in Figures 43 through 47 and like numerals are used to identify like components. As shown in Figures 48 and 49, the apparatus here comprises a low-profile, fluid-storage device which is substantially identical to the fluid storage device just described. Once again, in this latest embodiment, the cannula portion of the infusion means is integrally formed with the fluid storage device.

Fluid storage device 502 comprises a thin base 504 having a curved lower surface 504a which is disposed proximate the patient when the device is taped or otherwise removably affixed to the patient. Formed within base 504 is a generally circular shaped chamber 506 within which the heat-expandable means is carried. This heat-expandable means is somewhat different from that previously described, but still functions to controllably force the fluids contained within the sealed reservoir 508 of the device to flow outwardly through an outlet passageway formed in a cover 514 which is superimposed over and connected to base 506 in the manner best seen in Figure 49. The heat-expandable means, or member 517, which uniquely permits precise pattern delivery of fluid, is covered by a sealing means which here comprises a distendable membrane 466 which is sealably connected to the peripheral portion of base 504 in the manner indicated in Figure 49. As before, in this embodiment of the invention,



a second distendable membrane 468 overlays membrane 466 and is affixed to cover 514. In cooperation with a surface 514a formed in cover 514, membrane 426 forms the fluid reservoir 508 of the device. Fill means of the same character described in connection with the first embodiment of the invention are provided for introducing fluids into the reservoir 508, which is defined by surface 514a, through a fluid inlet 518 formed in cover 514. As the heat expandable means or semi-solid mass 70 is heated by the body heat of the patient, it will controllably expand causing any fluid contained within the reservoir to flow outwardly thereof through outlet passageway 510. When mass 70 expands, it will distend membranes 466 and 468 in a direction toward surface 514a (Figure 49). As barrier membrane 466 moves toward its distended configuration, it will closely conform to the shape of heat-expandable mass 517 resulting in a complete and controlled expelling of fluid from reservoir 508 through fluid outlet passageway 510 and into the infusion means 404 of the apparatus.

As shown in Figures \_\_\_ and \_\_\_, a novel aspect of the apparatus of this latter form of the invention is the previously mentioned intravenous infusion means which is shown here as an infusion assembly 517. Assembly 517 comprises an intravenous needle assembly 523 which includes a needle support 521 and a hollow needle 523 supported thereby. As best seen in Figure 49, needle support 521 is connected directly to cover 514 and extends angularly downward with respect to base 504. Once again, administration line shown in Figures 41 and 42 has been eliminated and support 521 functions to place reservoir 508 in communication with hollow needle 523 via still a different type of flow control means, the character of which will presently be described.

In using the apparatus of this latest form of the invention, reservoir 508 is filled with the beneficial agent to be infused into the patient using the fill means of the invention. This fill

means is of identical construction to that described in connection with the embodiment of Figures 13 through 15 and includes a septum 126 which comprises a non-corable material and which is held in position within cover 514 by a plastic septum cover 436 which is bonded to cover 514. As before, septum 126 is of standard construction and is penetrable by a cannula of a conventional type syringe which can be used to introduce fluid into inlet passageway 518 and thence into reservoir 508 the beneficial agent or medicinal fluid which is to be infused into the patient.

With reservoir 508 filled in the manner described, and with sheath 522 which covers needle 523 removed, the fluid delivery device can be interconnected with the patient in a manner such that cannula 523 pierces the patient's vein. The patient's body temperature will cause heat expandable mass 517 to expand causing the fluid contained within reservoir 508 to controllably flow under pressure toward outlet passageway 510 through the flow control means and into passageway 521a of support 521. The flow control means of this latest form of the invention, here comprises a novel, disk-like rate control member 527 having a central bore 527a. Member 527 is housed within a bore within a bore 527a of 529 formed in cover 514 (Figures 49 and 51). As best seen in Figures 49 and 51, member 527 is in communication with fluid passageway 510 and the central bore of cannula of 523. With this construction, fluid flowing into outlet passageway 460 will flow through a filter 529, through rate control member 527, and then into the inlet of hollow cannula 523. It is, of course, apparent that by carefully controlling the porosity of member 527 and the size of bore 527a, the rate of fluid flow toward the infusion means can be precisely controlled.

Turning to Figures 53 through 63, yet another form of the apparatus of the invention is there shown and generally designated by the numeral 550. This alternate embodiment is

somewhat similar to those earlier discussed herein and like numerals are used in Figures 53 through 63 to identify like components. However, in sharp contradistinction to the earlier embodiments of the invention, this latest apparatus includes a novel fluid storage device having a fluid reservoir which can either be filled by a septum assembly or by using a specially designed fluid container or vial assembly the character of which will presently be described.

As best seen by referring to Figures 53, 54, and 59, the apparatus here comprises a low-profile, fluid-storage device 552 and a remotely located cooperating infusion means 54 for infusing the fluid stored in device 552 into the patient. Infusion means 54 is identical to that previously described in connection with Figures 1 through 7. The fluid storage device 552, on the other hand, is of a slightly different construction in that it includes not only the novel vial fill feature, but also is designed to mate with a quick coupling mechanism of a somewhat different character, which is releasably connected to the fluid storage device by a push button type capture and release assembly 553.

Fluid storage device 552 here comprises a thin base assembly 554 having a central portion 554a and peripheral portion 554b circumscribing central portion 554a. As before, base assembly 554 is provided with a curved lower surface 554c of the character best seen in Figures 54 and 59. In use, surface 554c is disposed proximate the patient so that the device can be taped or otherwise removably affixed to the patient, such as by using a foam adhesive tape 555 which has an adhesive "A" provided on both sides of the tape. Once again, where appropriate, a peelable film can be provided to protect the lower adhesive covered surface of tape 555 until time of use.

Formed within base assembly 554 is a generally circular shaped opening 556 which receives a heat-expandable means of the general character previously described. This

heat-expandable means functions to controllably force the fluids contained within the sealed reservoir 560 of the device (Figure 54) to flow outwardly through an outlet passageway 562 formed in a cover 564 which is superimposed over base assembly 554 in the manner shown in Figures 54 and 59. The heat-expandable means is held in position within opening 556 by a floor-like member 566 which forms a part of the base assembly 554 and preferably is insert molded to a base component 567 which also forms a part of the base assembly. Member 566 is typically constructed of a heat conductive metal such as aluminum or stainless steel which can be stamped into the required configuration and can function as an effective heat sink.

As in the previously described embodiments, the heat expandable means or mass 569 is covered by a sealing means comprising a membrane 72 which is sealably connected to the peripheral portion 554a of the base assembly by any suitable means such as thermal bonding. Overlaying membrane 72 and bonded to a cover 564 by any suitable means is a distendable membrane 74 which, in cooperation with a generally concave shaped cavity 564a formed in cover 564 forms fluid reservoir 560 (Figure 54).

As previously mentioned, fill means of a totally different character from that described in connection with the earlier embodiments of the invention is here provided. While, as before, the fill means functions to introduce fluids into reservoir 560, the fill means here comprises a novel vial fill subassembly, generally identified in the drawings by the numeral 570, and a pierceable septum subassembly generally designated as 571. Both of these fill subassemblies communicate with a fluid inlet passageway 572 formed in cover 564.

Referring particularly to Figures 59 and 60, the vial fill subassembly 570 here comprises a container 572 which includes a hollow body portion 574, having first and second open ends 574a and 574b. First open end 574a is sealably closed by closure means here

provided in the form of a pierceable member 576 which is held in sealing engagement with body portion 574 by a clamping ring 578 (Figure 60). A plunger 580 is telescopically movable within hollow body portion 574 from a first location proximate second open end 574b to a second position proximate first open end 574a. Body portion 574 of fill subassembly 570 can be constructed from various materials such as glass and plastic.

Also forming a part of the vial fill subassembly 570 of the invention, is an adapter component 582 which comprises a housing 584 having a first open end 584a and a second closed end 584b (Figure 60). As indicated in Figures 53 and 61, container 572 is telescopically receivable within open end 584a of housing 584 so that the housing can be moved from the first extended position shown in Figure 59 to a second, container encapsulation position wherein hollow body portion 574 is substantially encapsulated within the adapter component. Also forming a part of the adapter component 582 is pusher means shown here as a pusher member 582a (Figure 61) which, in a manner presently to be described, functions to engage and move plunger 580 longitudinally of body portion 574 from the first extended position to a second inserted position.

Turning once again to Figures 53, 54, and 59, cover assembly 564 of the fluid storage device can be seen to include a side portion 564a having an elongated receiving chamber 564b which is adapted to receive the vial fill subassembly 570 of the invention. When the vial fill subassembly is in position within chamber 564b, the fluid chamber of the subassembly communicates with reservoir 560 via passageways 588, 590, 592, 594, and 572 (Figures 53 and 58). As shown in Figure 58, passageways 590 and 592 are formed within cover portion 564a, while passageway 588 is formed within a piercing cannula 596 which is connected to and extends from a generally cup-shaped closure member 598 which functions to close the inboard

end of receiving chamber 564b. As best seen in Figure 58, cannula passageway 588 communicates with a chamber 600 which, in turn, communicates with passageway 590 via valve means, shown here as an umbrella valve assembly 592. Valve assembly 592 includes a body portion 592a which is connected to cover portion 564a and a resiliently deformable, umbrella-like member 592b which is disposed within chamber 600 and is movable from a valve closed position to a valve open position in response to fluid flowing through cannula 596 through passageways 593 formed in body portion 592a, into chamber 600 and then toward passageway 590. However, the construction of umbrella-like member 592b is such that it effectively blocks fluid flow in an opposite direction.

In using the apparatus of the invention, with the fluid chamber of container 572 filled with the desired beneficial agent, the vial fill subassembly 570 is telescopically inserted into receiving chamber 654b of cover 654 and is pushed inwardly with sufficient force to cause the piercing cannula 596 to pierce sealing member 576 of the container assembly. Once a fluid flow path between the fluid chamber of the container assembly and the fluid reservoir 560 is thus created, a continued inward movement of the adapter component over the container body 574 will cause pusher member 584b to engage and controllably move plunger 580 inwardly of hollow body 574. As plunger 580 moves inwardly of the hollow body, the fluid contained therewithin will flow toward end 574a, through passageway 588 of the piercing cannula 596 and then into chamber 600. The fluid under pressure will cause the umbrella valve 592 to open so that fluid can flow into fluid reservoir 560 via passageways 590, 592, 594 and 572. Once reservoir 560 is filled, either with fluid introduced via the pierceable septum subassembly 571, or with fluid flowing from the vial fill subassembly 570 of the fill means or by a combination of both, the fluid will remain in the reservoir of the fluid storage device until time

of use.

Referring particularly to Figures 60 and 61, it is to be noted that adapter component 582 includes locking means for locking housing 584 within receiving chamber 564b of cover portion 564a after the vial fill subassembly has been mated with the fluid storage device. These locking means are here provided in the form of a series of longitudinally spaced locking teeth 604. These locking teeth are constructed so that they will slide under a flexible locking tab 606, which is provided proximate the entrance of receiving chamber 564b as the adapter component is urged inwardly of receiving chamber 564b. However, once the adapter subassembly has reached the fully inserted position and the fluid contained within the container 574 has been transferred to reservoir 560, locking tab 606 will spring back to its locking position and in so doing will effectively prevent removal of the adapter component from chamber 564b. With this novel construction, once reservoir 560 has been filled with the fluid contained within container 574, the vial fill assembly cannot be removed from receiving chamber 564b and, therefore, cannot be reused thereby preventing system alteration.

With reservoir 560 filled with the fluid to be infused into the patient and with the fluid storage device affixed to the patient, the body heat of the patient will cause the heat expandable means or mass 569 to controllably expand causing the fluid contained within the reservoir to flow outwardly thereof through outlet passageway 562. As before, when mass 569 expands, it will distend sealing membrane 72 and distendable membrane 74 in a direction toward inner wall of cavity 564 (Figure 54). It is to be noted that as membranes 72 and 74 move toward their distended configuration, they will closely conform to the resulting geometry of heat-expandable mass 569 resulting in a complete and controlled expelling of fluid from reservoir 560 through fluid outlet passageway 562 and into the infusion means 54 of the

apparatus which is identical to that previously described in connection with the embodiment of the invention shown in figures 1 through 24.

As best seen in Figures 53, 56, and 57, the remotely located infusion means 54 is interconnected with the fluid storage device by a novel quick connect and release means 572 of a quite different construction to those previously described is here provided. This novel means, which includes the previously mentioned push button type capture and release assembly 553, enables quick interconnection of the administration line 108 of the infusion means with cover 564 so that the line is placed in fluid communication with outlet passageway 562 of reservoir 560. More particularly, as shown in Figure 53, administration line 108 is connected to the connector member 612 of the quick connect and release means which includes an oval body portion 614. Connected to body portion 614 is a nipple 616 which is closely received within a socket 618 formed in cover 564 (Figures 53 and 54). Also formed in cover 564 is an oval aperture 620 which is adapted to receive a push button 622 of assembly 653. As best seen in Figure 56, a pair of resiliently deformable, downwardly extending, spaced-apart arms 624 are attached to push button 622 by living hinges 624a. The extremities of arms 624 are adapted to slidably engage a wedge-like protuberance 626 formed on base 567 so that when push button 622 is depressed, arms 624 will spread apart a distance sufficient to permit a shoulder 612a formed on connector 612 to pass between arms 624. As shown in Figure 56A, when arms 624 are spread apart, shoulder 612a, which is oval in cross section, will pass between the arms. When the arms spring back to their normal position, they will engage reduced diameter portion 614a and thereby lock ullage 616 in position within socket 618. When it is desired to separate the infusion set 54 from the fluid storage device, a downward finger pressure exerted on push button 553 will once again spread arms 624 apart a distance



sufficient to permit passage of shoulder 612a and removal of nipple 616 from socket 618.

After the fluid from reservoir 560 has been infused into the patient, the reservoir can be refilled if desired using the pierceable septum subassembly 571 of the fill means of the invention. As before, the elastomeric septum component 571a of the septum subassembly is held in position within cover 564 by a clamping ring 571b (Figure 58). Septum 571 is of a conventional non-coring elastomeric material construction and is penetrable by a cannula "C" of a syringe of conventional construction. As before, a conventional syringe (not shown) can be used to introduce fluid to be dispensed into inlet passageway 592, into passageway 594, and thence into reservoir 180 via passageway 572.

Referring to Figures 62 and 63, an alternate form of the cover mounted piercing cannula assembly of the invention is there shown and generally identified by the numeral 630. This assembly which is similar to that previously described also includes a generally cup shaped member 632 which is connected to cover 564 proximate the inboard end of receiving chamber 564b. A hollow needle 634 is insert molded into member 632 and extends therefrom. As shown in Figure 62, a plurality of circumferentially spaced protuberances 632a which are formed on inner wall 632b of member 632, support and function to elevate an umbrella type check valve of the character previously described so as to permit fluid to freely flow beneath the base of the check valve past protuberances 632a and into chamber 600. Protuberances 632a preclude the necessity of providing fluid flow passageways 593 within the body portion of the valve.

Turning to Figures 64 through 69, still another form of the fluid delivery apparatus of the invention is there shown and generally designated by the numeral 650. This alternate embodiment is similar to that shown in Figures 53 through 63 and like numerals are used in

Figures 64 through 69 to identify like components. As best seen in Figures 64 and 65, this latest apparatus also comprises a fluid storage device having a fluid reservoir which can either be filled by a septum assembly or by using a fluid container or vial assembly the character previously described. However, in this latest embodiment of the invention, the infusion means is provided as a part of the fluid storage device rather than comprising a remotely located infusion device such as the previously describe assemblage 54.

Like the embodiment of the invention shown in figures 53 through 62, the fluid storage device here comprises a thin base assembly 654 having a central portion 654a and peripheral portion 654b circumscribing central portion 654a. As before, the base assembly is provided with a curved lower surface 654c which can be located proximate the patient so that the device can be taped or otherwise removably affixed to the patient, such as by using a foam adhesive tape 555.

Formed within base assembly 654 is a generally U-shaped opening 656 (Figure 69) which receives the heat-expandable means of the invention. Once again, this heat-expandable means functions to controllably force the fluids contained within the sealed reservoir 660 of the device (Figure 64) to flow outwardly through an outlet passageway 661 formed in the base assembly. As shown in figure 66 passageway 661 is closed at its outbound end by a small closure plug 661a.

Also formed within base assembly 664 is a cannula receiving channel 666 (Figures 64 and 65) within which the body portion 668a of a novel spiral-like hollow cannula or capillary 668 is uniquely mounted in a manner presently to be described.

The previously mentioned heat expandable means is here provided in the form of a generally U-shaped temperature expandable member 672 which is disposed within cavity 656

in the manner best illustrated in Figure 69. Superimposed over cavity 656 and expandable member 672 is a sealing means which here comprises an elastomeric membrane 676 which is sealably connected to a strategically shaped floor 678 which forms a part of base assembly 654. Floor 678, which is preferably provided in the form of a metal stamping, forms a part of the base assembly, and, as before, functions as an efficient heat sink. Overlaying membrane 676 is a distendable membrane 680 which, in cooperation with a generally concave shaped surface 664a formed on cover 664, forms the fluid reservoir 660. As in the earlier described embodiments, as member 672 is heated by the patient's body, it will controllably expand from its normal, relaxed configuration to an expanded configuration. As member 672 expands into the expanded configuration, it will distend sealing membrane 676 as well as distendable membrane 680 in a direction toward concave inner wall 664a of a cover 664 and will cause the fluid contained within the fluid reservoir to flow outwardly through the infusion means or cannula 668.

In addition to cannula 668, the infusion means also comprises flow control means for controlling fluid flow into cannula 668. This flow control means, which includes rate control means and cooperating filter means, is identical to that described in connection with the embodiment shown in Figures 25 through 28 and includes a porous rate control member 304 and a porous filter 306 (see also Figure 27). As before, the flow control means is disposed between the outlet of the reservoir 660 and an inlet passageway 684 formed in the periphery of the base assembly 654. Cannula 668 includes an inlet end 668c which communicates with passageway 684 (Figure 66) and an outlet end 668b, which comprises a needle-like segment that extends generally perpendicularly downward from infusion of medicinal fluids into the patient. For this purpose, outlet end 668b is provided with a sharp, pointed extremity. To

maintain the outlet end in a sterile condition, a protective sheath 686 is provided. Sheath 686 surrounds the outwardly extending cannula segment and is removably affixed to floor 678 in the manner previously described and as shown in Figure 65.

Turning once again to Figures 64 and 65, it is to be observed that part of the body portion 668a of spiral cannula 668 is uniquely supported within channel 666 of the base assembly by a cannula encapsulation means shown here as a standard potting compound "P". As in the earlier described embodiments of the invention, compound "P" rigidly supports the body portion of the cannula within channel 666 and dynamically supports the outer extremity of the cannula body so that the free end portion of the cannula can move three dimensionally within channel 660. With this construction, when the device is connected to the patient, normal movement by the patient will permit the cannula to move within a portion of channel 666 while the base and heat shield components of the base assembly remain completely stationary.

As previously mentioned, the fill means is substantially identical to the fill means of the embodiment shown in Figures 53 through 63 and comprises the vial fill subassembly 570 and the pierceable septum subassembly 571. Both of these fill subassemblies communicate with a fluid inlet passageway 690 formed in cover 664.

Referring particularly to figures 65, 67, and 69, the vial fill subassembly 570 is identical to that previously described and includes a container component 572 and an adapter component 582. As before, container 572 is telescopically receivable within open end 584a of housing 584 of adapter component 582 so that the housing can be moved from a first extended position to a second, container encapsulation position.

As shown in Figures 64, 65 and 69, cover assembly 664 of the fluid storage device

includes a side portion 664a having an elongated receiving chamber 664b which is adapted to receive the vial fill subassembly 570 of the invention. As before, when the vial fill subassembly is in position within chamber 664b, the fluid chamber of the subassembly communicates with reservoir 660 via passageways 588, 590, 594 and 690 (Figure 64). As shown in Figure 64, passageways 590 and 592 are formed within cover portion 664a, which passageway 588 is formed within the cover mounted piercing cannula which is connected to and extends from a generally cup-shaped closure member 598 which functions to close the inboard end of receiving chamber 664b. As before, cannula passageway 588 communicates with a chamber 600 which, in turn, communicates with passageway 590 via valve means, or umbrella valve assembly 592 which is identical to that previously described.

Use of the apparatus of the invention, to fill reservoir 660 is basically as previously described in connection with the apparatus shown in Figures 53 through 63 and this reservoir filling sequence need not be repeated.

Once the reservoir has been filled with the fluid to be infused into the patient and the fluid storage device has been affixed to the patient by piercing the patient's skin and tissue with the downwardly depending cannula portion 668a, the body heat of the patient will cause the heat expandable means or mass 672 to controllably expand causing the fluid contained within the reservoir to flow outwardly thereof through outlet passageway 684. the fluid will then flow into the infusion means or cannula 668 via the flow control means which comprises filter 306 and rate control 304.

After the fluid from reservoir 660 has been infused into the patient, the reservoir can, in the manner previously described, using the pierceable septum subassembly 571 of the fill means of the invention.

Having now described the invention in detail in accordance with the requirements of the patent statutes, those skilled in this art will have no difficulty in making changes and modifications in the individual parts or their relative assembly in order to meet specific requirements or conditions. Such changes and modifications may be made without departing from the scope and spirit of the invention, as set forth in the following claims.

## I CLAIM

1. A device for use in infusing medicinal fluid into a patient at a controlled rate comprising:

(a) a housing having a rigid surface;

(b) distendable means for forming, in conjunction with said rigid surface of said housing, a fluid reservoir having an inlet and an outlet. said distendable means comprising at least one distendable member at least a portion of which is movable within said housing from a first position to a second position;

(c) heat expandable means disposed within said housing in proximity to said distendable membrane, said heat expandable means comprising a semi-solid, which, upon being heated, will act upon said distendable membrane to move said membrane toward said second position to cause fluid within said reservoir to flow outwardly of said outlet of said reservoir; and

(d) infusion means in communication with said outlet of said reservoir for infusing fluid from said fluid reservoir into the patient.

2. A device as defined in Claim 1 in which said heat expandable means comprises a heat expandable gel.

3. A device as defined in Claim 1 in which said distendable membrane substantially conforms to said heat expandable means as said heat expandable means is heated.

4. A device as defined in Claim 1 in which said infusion means comprises a subcutaneous infusion device connected to and spaced apart from said housing for infusing fluid from said reservoir into said patient.

5. A device as defined in Claim 1 in which said housing includes fill means.
6. A device as defined in Claim 1 in which said housing comprises a base defining a heat sink and a cover superimposed over said base, said heat expandable means being disposed between said heat sink and said cover.
7. A device as defined in Claim 6 in which said infusion means comprises a hollow cannula connected to said base and extending therefrom.
8. A device as defined in Claim 6 further including flow control means carried by said housing for controlling fluid flow from said fluid reservoir toward said infusion means.
9. A device as defined in Claim 6 in which said heat expandable means is carried by said base and in which said distendable membrane overlays said heat expandable means and is connected to said base.
10. A device as defined in Claim 9 further including a second distendable membrane overlaying said first distendable membrane, said second distendable membrane being connected to a selected one of said base and said cover.
11. A device for use in infusing medicinal fluid into a patient at a controlled rate comprising:
  - (a) a housing having surface and a fluid flow channel, said housing comprising a base and a cover superimposed over said base;
  - (b) distendable means for forming, in conjunction with said surface of said housing, a fluid reservoir having an outlet, said distendable means comprising at least one distendable member disposed between said cover and said base, at least a portion of said member being movable within said housing from a first position to a second position;
  - (c) heat expandable means disposed within said housing in proximity with said



distendable membrane, said heat expandable means, upon being heated, acting upon said distendable membrane to move said membrane toward said second position to cause fluid within said reservoir to flow outwardly of said outlet of said reservoir;

(d) infusion means in communication with said outlet of said reservoir for infusing fluid from said fluid reservoir into the patient; and

(e) flow control means in communication with said outlet of said reservoir for controlling fluid flow toward said infusion means.

12. A device as defined in Claim 11 further comprising flow control means in communication with said outlet of said reservoir for controlling fluid flow toward said infusion means.

13. A device as defined in Claim 11 in which said distendable membrane substantially conforms to said heat expandable means as said heat expandable means is heated.

14. A device as defined in Claim 11 in which said cover includes a substantially concave surface, said distendable membrane cooperating with said concave surface to define said reservoir.

15. A device as defined in Claim 11 further including flow indicator means disposed within said reservoir for indicating fluid flow from said reservoir.

16. A device as defined in Claim 11 in which said infusion means comprises a hollow cannula in communication with said outlet of said reservoir.

17. A device as defined in Claim 11 in which said infusion means comprises a subcutaneous infusion device connected to and spaced apart from said housing for infusing fluid from said reservoir into said patient, said subcutaneous infusion device including a body

having an internal chamber and a hollow cannula connected to said body.

18. A device as defined in Claim 17 in which said hollow cannula includes:

- (a) an inlet end portion;
- (b) a central body portion communication with said inlet end portion and disposed within said internal chamber for movement therewithin relative to said body; and
- (c) an outlet end portion comprising a pierceable portion extending outwardly from said body for insertion into the patient.

19. An apparatus as defined in Claim 17 further including cannula encapsulation means for encapsulating and immovably constraining said inlet end portion of said hollow cannula within said body and for dynamically supporting said outlet end portion of said cannula.

20. A device as defined in Claim 19 in which said base and said subcutaneous infusion device are connected together by an elongated fluid delivery tube.

21. A device as defined in Claim 19 in which said body of said subcutaneous infusion device includes a base and a cover connected to said base, said cover cooperating with said base to define said internal chamber.

22. A device as defined in Claim 21 in which said subcutaneous delivery device further includes a cover assembly removably connected to said base for covering said outlet end portion of said cannula.

23. A device for use in infusing medicinal fluid into a patient at a controlled rate comprising:

- (a) a housing having a rigid surface;
- (b) distendable means for forming, in conjunction with said rigid surface of said

housing, a fluid reservoir having an inlet and an outlet. said distendable means comprising at least one distendable member at least a portion of which is movable within said housing from a first position to a second position;

(c) a heat expandable gel disposed within said housing in proximity to said distendable membrane, said heat expandable gel, upon being heated, acting upon said distendable membrane to move said membrane toward said second position to cause fluid within said reservoir to flow outwardly of said outlet of said reservoir; and

(d) fill means in communication with said inlet of said fluid reservoir for filling said reservoir with fluid; and

(e) infusion means in communication with said outlet of said reservoir for infusing fluid from said fluid reservoir into the patient.

24. A device as defined in Claim 23 in which said infusion means comprises a subcutaneous infusion device connected to and spaced apart from said housing for infusing fluid from said reservoir into said patient.

25. A device as defined in Claim 23 in which said distendable membrane substantially conforms to said heat expandable gel as said heat expandable means is heated.

26. A device as defined in Claim 23 in which said heat expandable gel comprises a phase-transition gel.

27. A device as defined in Claim 23 in which said heat expandable gel comprises an ionized acrylamide gel composition.

28. A device as defined in Claim 23 in which heat expandable get comprises an interpenetrating polymer network.

29. A device as defined in Claim 23 in which said fill means comprises a pierceable

septum carried by said housing.

30. A device as defined in Claim 23 in which said fill means comprises a liquid container interconnectable with said housing.

31. A device as defined in Claim 30 in which said housing includes a receiving chamber for telescopically receiving said liquid container.

32. A device as defined in Claim 31 in which said receiving chamber is provided with a piercing cannula in communication with said reservoir and in which said liquid container includes a sealing member pierceable by said piercing cannula.

33. A device for use in infusing medicinal fluid into a patient at a controlled rate comprising:

- (a) a housing having a rigid surface;
- (b) distendable means for forming, in conjunction with said rigid surface of said housing, a fluid reservoir having an inlet and an outlet, said distendable means comprising at least one distendable member at least a portion of which is movable within said housing from a first position to a second position;
- (c) heat expandable means disposed within said housing between said rigid surface and said distendable membrane, said heat expandable means comprising a semi-solid, which, upon being heated, will act upon said distendable membrane to move said membrane toward said second position to cause fluid within said reservoir to flow outwardly of said outlet of said reservoir;
- (d) infusion means in communication with said outlet of said reservoir for infusing fluid from said fluid reservoir into the patient; and
- (e) means for interconnecting said infusion means with said housing.

34. A device as defined in Claim 33 in which said heat expandable means comprises a heat expandable gel.

35. A device as defined in Claim 33 in which said heat expandable means comprises a composite of materials which expand at different rates.

36. A device as defined in Claim 33 in which said infusion means comprises a fill septum mounted on said housing.

37. A device as defined in Claim 33 in which said infusion means comprises a subcutaneous infusion device connected to and spaced apart from said housing for infusing fluid from said reservoir into said patient.

38. A device as defined in Claim 33 further including flow indicator means for indicating fluid flow from said reservoir.

39. A device as defined in Claim 33 in which said infusion means comprises a septum mounted on said housing.

40. A device as defined in Claim 33 in which said infusion means comprises a subcutaneous infusion device connected to and spaced apart from said housing for infusing fluid from said reservoir into said patient.

41. A device as defined in Claim 40 in which said infusion means comprises an elongated fill tube and in which said means for interconnecting said infusion means with said housing comprises a quick connect mechanism for quickly interconnecting said fill tube with said housing.

42. A device as defined in Claim 41 in which said housing is provided with a socket and in which said quick connect mechanism comprises:

- (a) a hub at least partially receivable in said socket in said housing; and

- (b) at least one yieldably deformable arm connected to said hub for releasably gripping said housing.

43. A device as defined in Claim 41 in which said housing is provided with a socket and in which said quick connect mechanism comprises:

- (a) a hub at least partially receivable in said socket in said housing; and
- (b) a yieldably deformable arm connected to said housing for releasably engaging said hub.

44. A device as defined in Claim 41 in which said housing is provided with a socket in communication with said reservoir and in which said quick connect mechanism comprises:

- (a) a hub at least partially receivable in said socket; and
- (b) release means for releasably locking said hub in position within said socket

45. A device as defined in Claim 44 in which said release means comprises a push button assembly connected to said cover.

46. A device for use in infusing medicinal fluid into a patient at a controlled rate comprising:

- (a) a housing having a rigid surface;
- (b) distendable means for forming, in conjunction with said rigid surface of said housing, a fluid reservoir having an inlet and an outlet, said distendable means comprising at least one distendable membrane at least a portion of which is movable within said housing from a first position to a second position;
- (c) heat expandable means disposed within said housing between said rigid surface and said distendable membrane, said heat expandable means comprising a plurality of polymers each of which, upon being heated, will act upon said distendable membrane to

move said membrane toward said second position to cause fluid within said reservoir to flow outwardly of said outlet of said reservoir; and

(d) infusion means in communication with said outlet of said reservoir for infusing fluid from said fluid reservoir into the patient.

47. A device as defined in Claim 46 in which said heat expandable means comprises a laminated assemblage of said polymers.

48. A device as defined in Claim 46 in which said heat expandable means comprises a blend of said polymers which expand at different rates as a function of time.

49. A device as defined in Claim 46 in which said polymers comprises phase-transition gel.

50. A device as defined in Claim 46 in which said plurality of polymers comprise at least two phase transition gel laminates of different thickness.

51. A device for use in infusing medicinal fluid into a patient at a controlled rate comprising:

(a) a housing having a rigid surface;

(b) distendable means for forming, in conjunction with said rigid surface of said housing, a fluid reservoir having an inlet and an outlet. said distendable means comprising at least one distendable membrane at least a portion of which is movable within said housing from a first position to a second position;

(c) a heat-expandable, three-dimensional gel network disposed within said housing in proximity to said distendable membrane, said heat expandable gel, upon being heated, changes in volume so as to act upon said distendable membrane to move said membrane toward said second position to cause fluid within said reservoir to flow

outwardly of said outlet of said reservoir; and

(d) fill means in communication with said inlet of said fluid reservoir for filling said reservoir with fluid;

(e) infusion means in communication with said outlet of said reservoir for infusing fluid from said fluid reservoir into the patient; and

(f) flow control means disposed between said outlet of said reservoir and said infusion means for controlling fluid flow toward said infusion means.

52. A device as defined in Claim 51 in which said flow control means comprises filter and a flow rate control means.

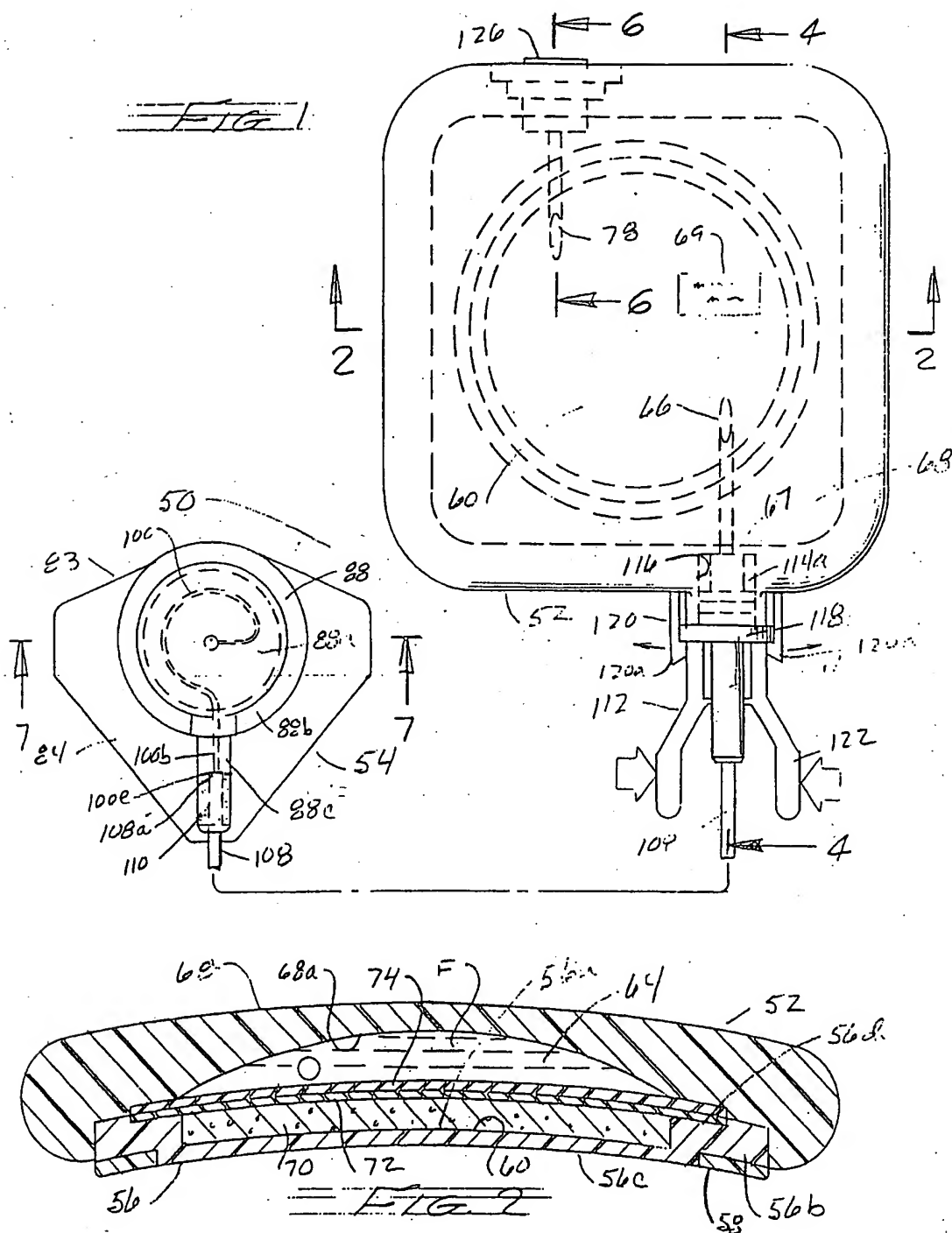
53. A device as defined in Claim 51 in which said flow control means comprises a capillary having a fixed length and diameter mounted between said reservoir and said infusion means.

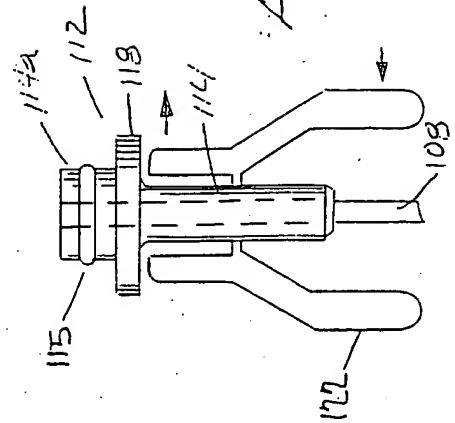
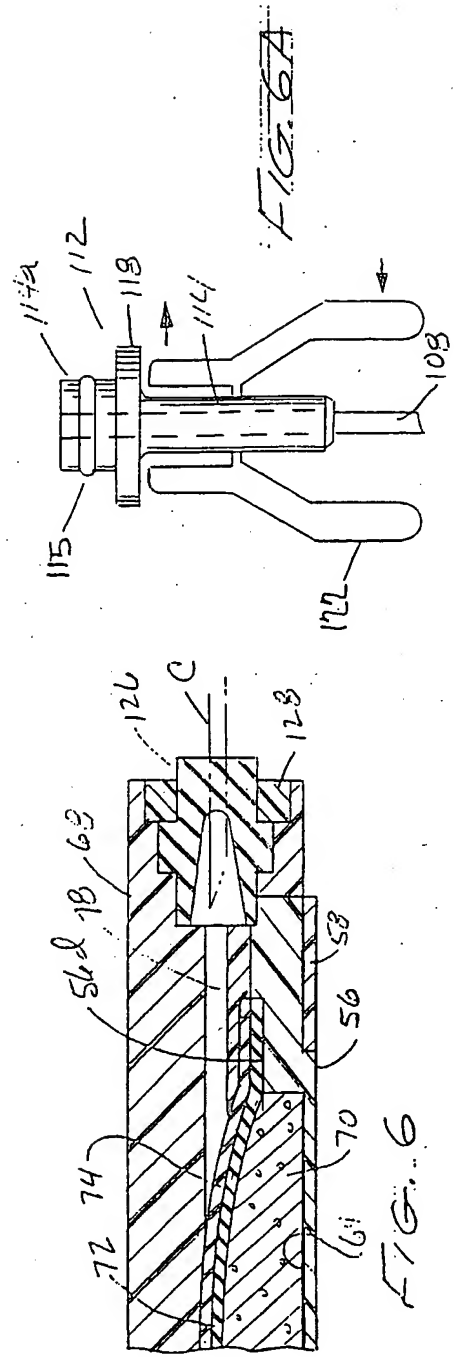
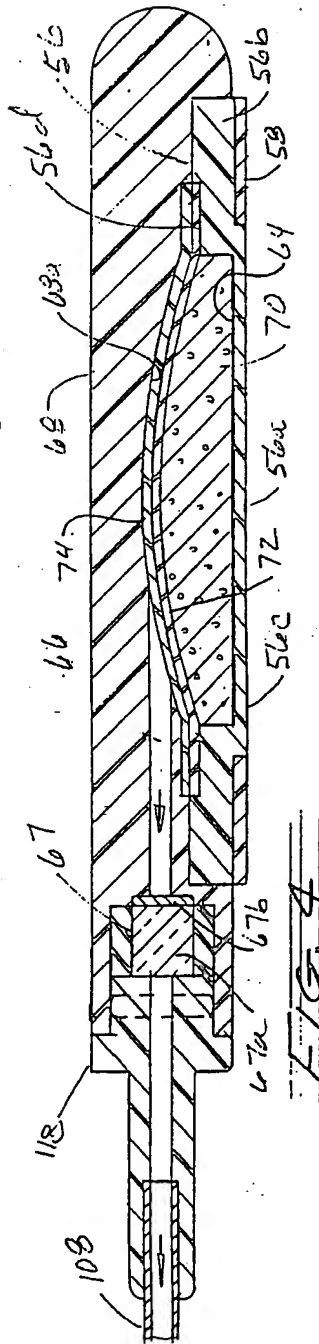
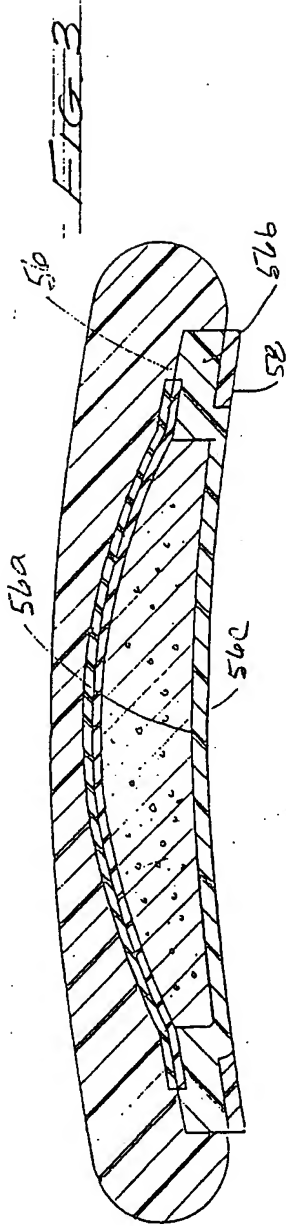
54. A device as defined in Claim 51 in which said flow control means comprises a micro-porous membrane mounted within said housing.

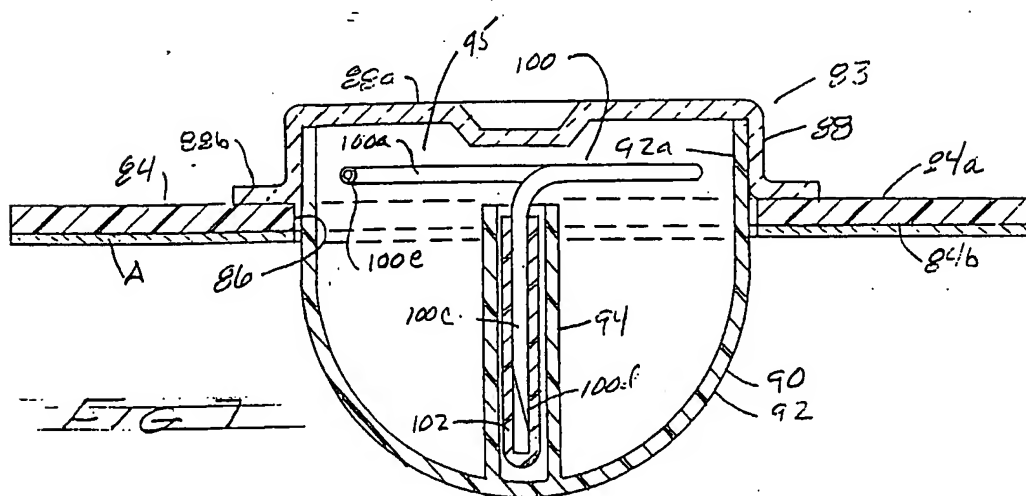
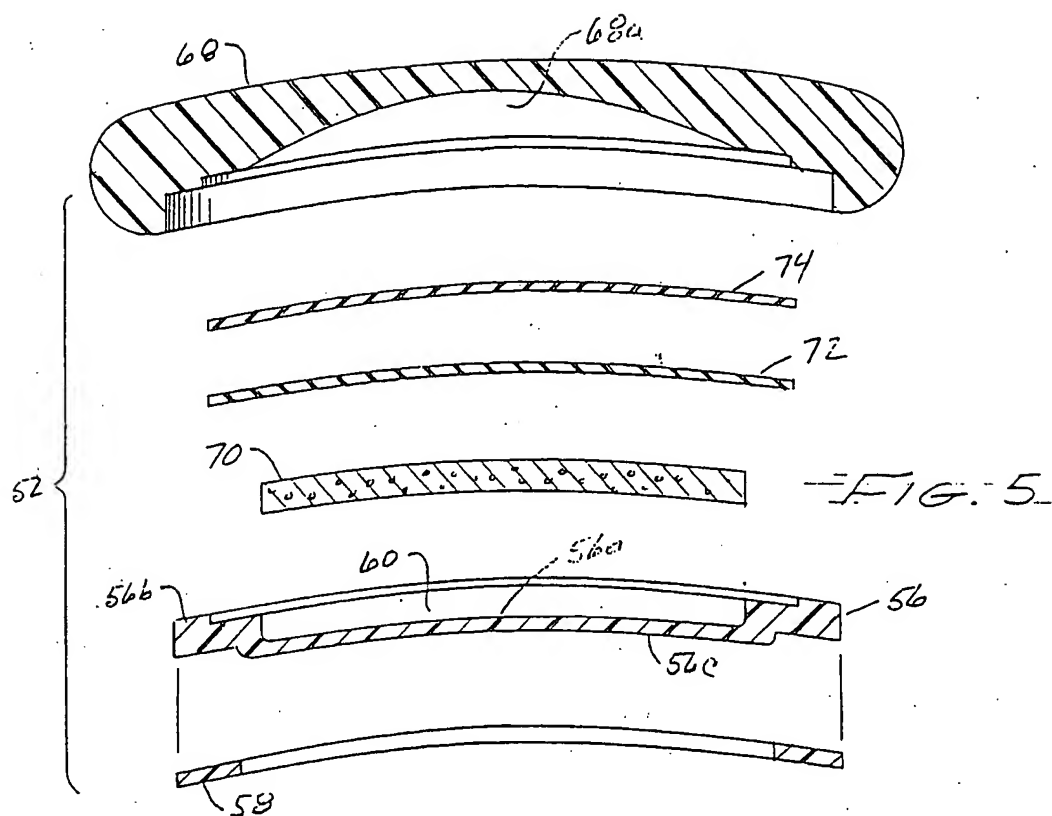
55. A device as defined in Claim 51 in which said flow control means comprises a permeable membrane mounted within said housing.

56. A device as defined in Claim 51 in which said flow control means comprises a membrane having an aperture of a fixed diameter.









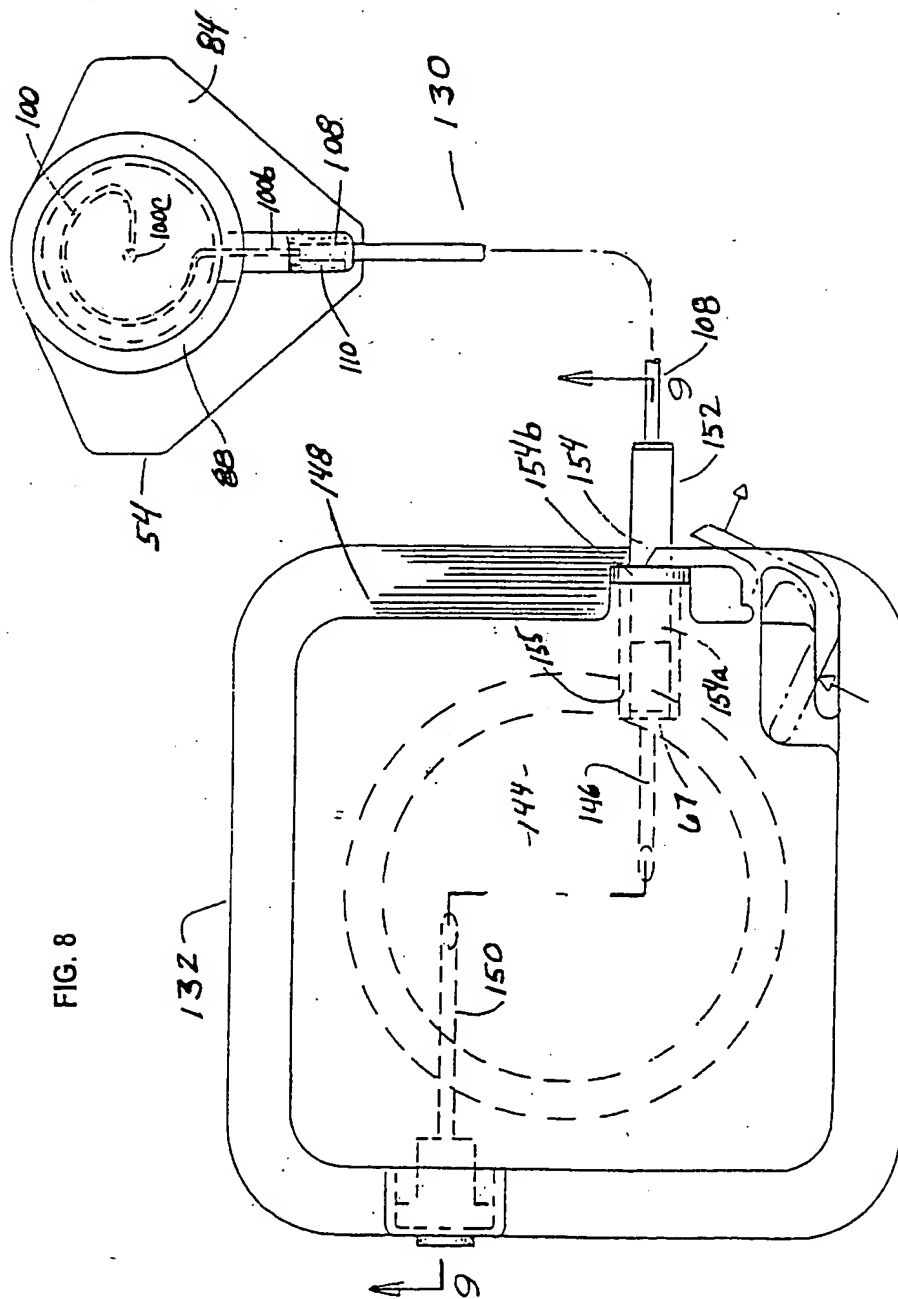


FIG. 8

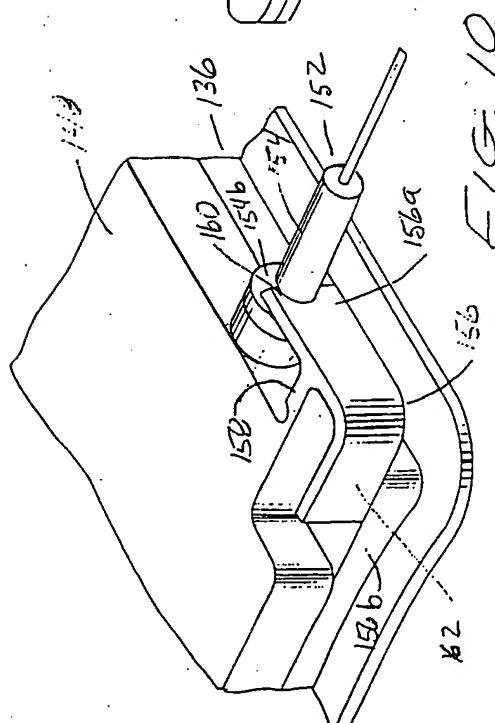
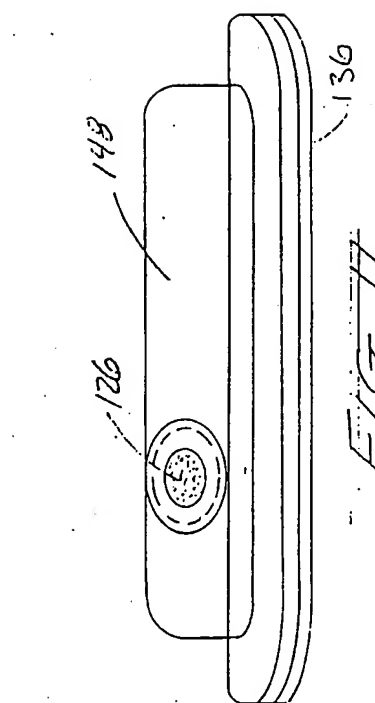
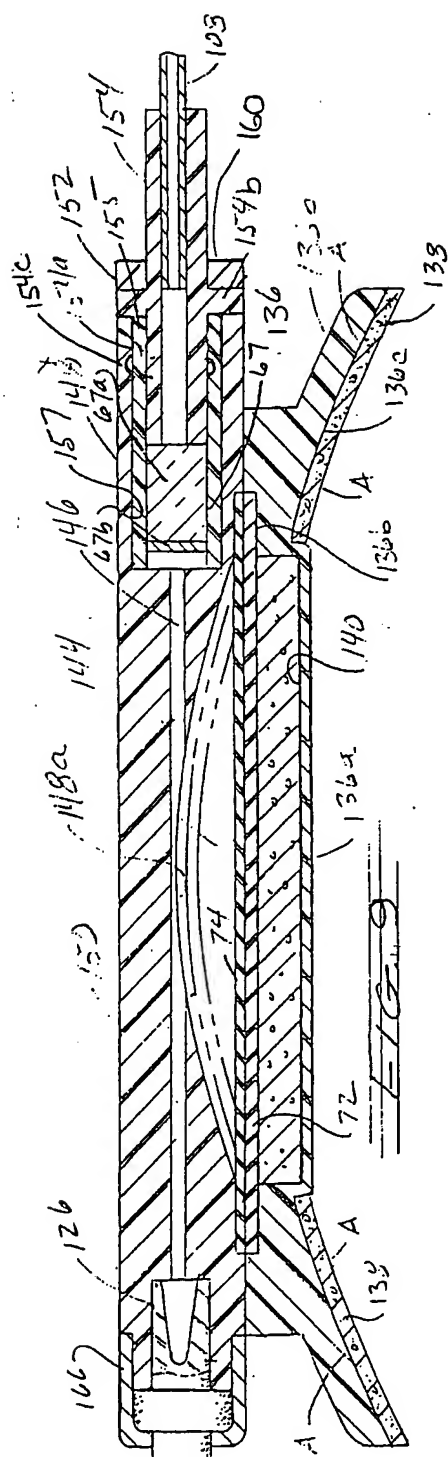
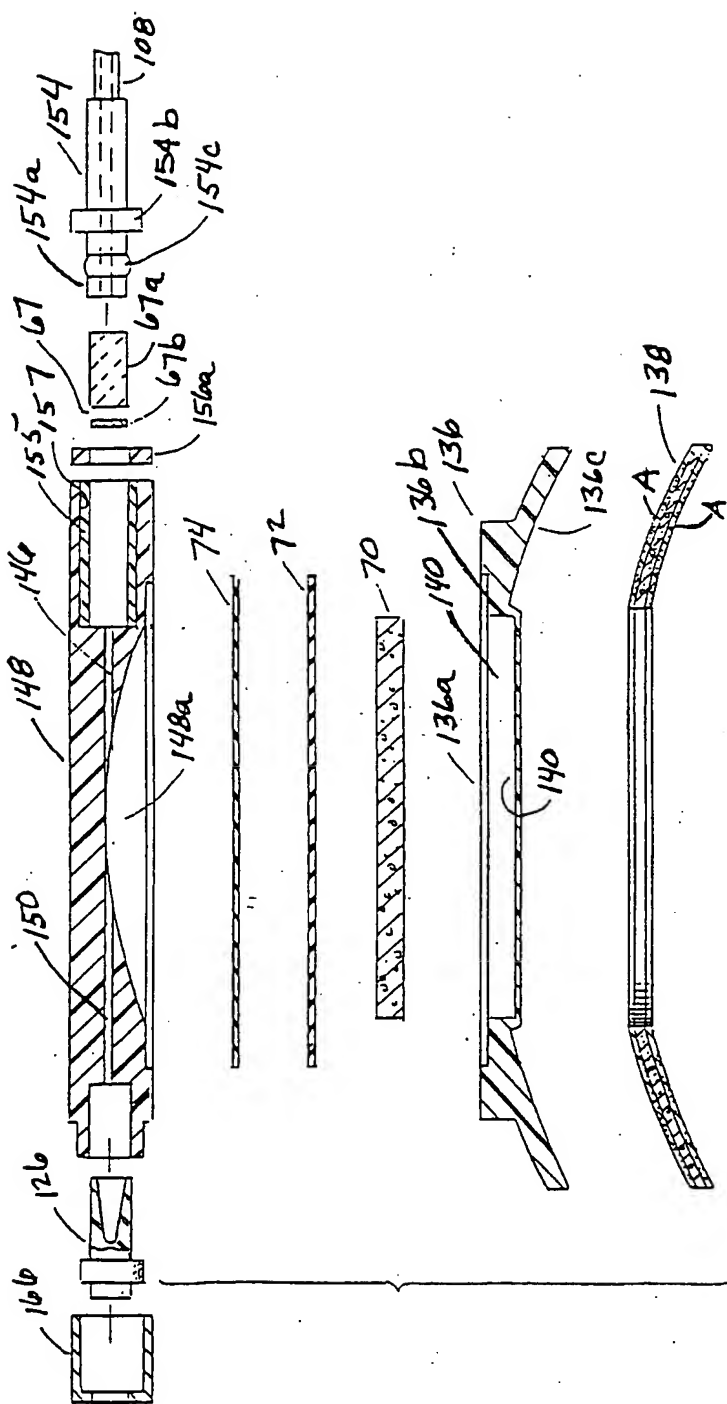


FIG. 12



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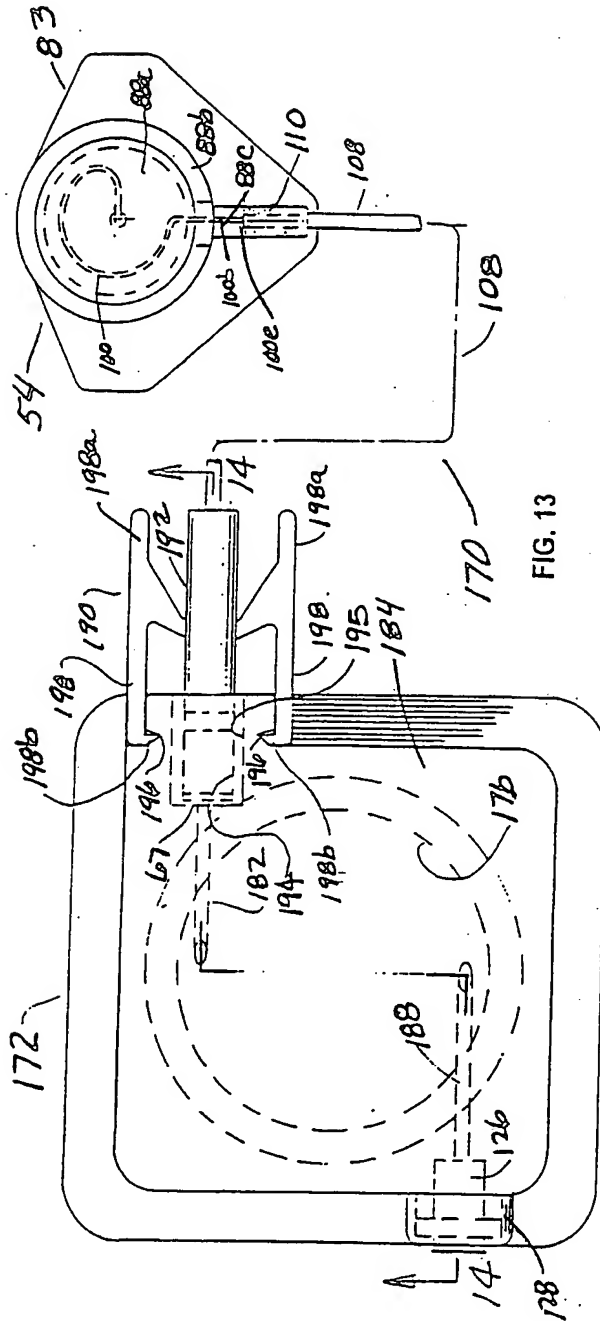


FIG. 13

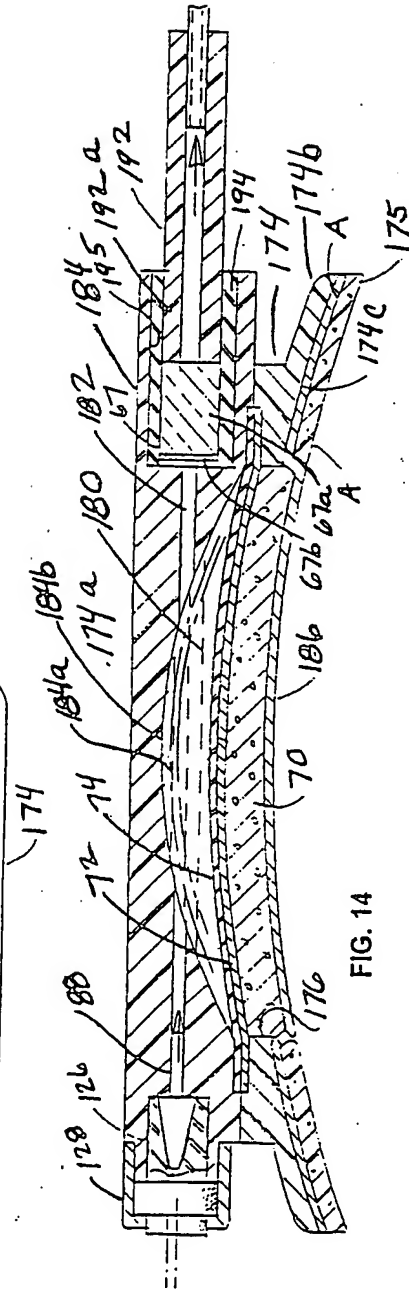
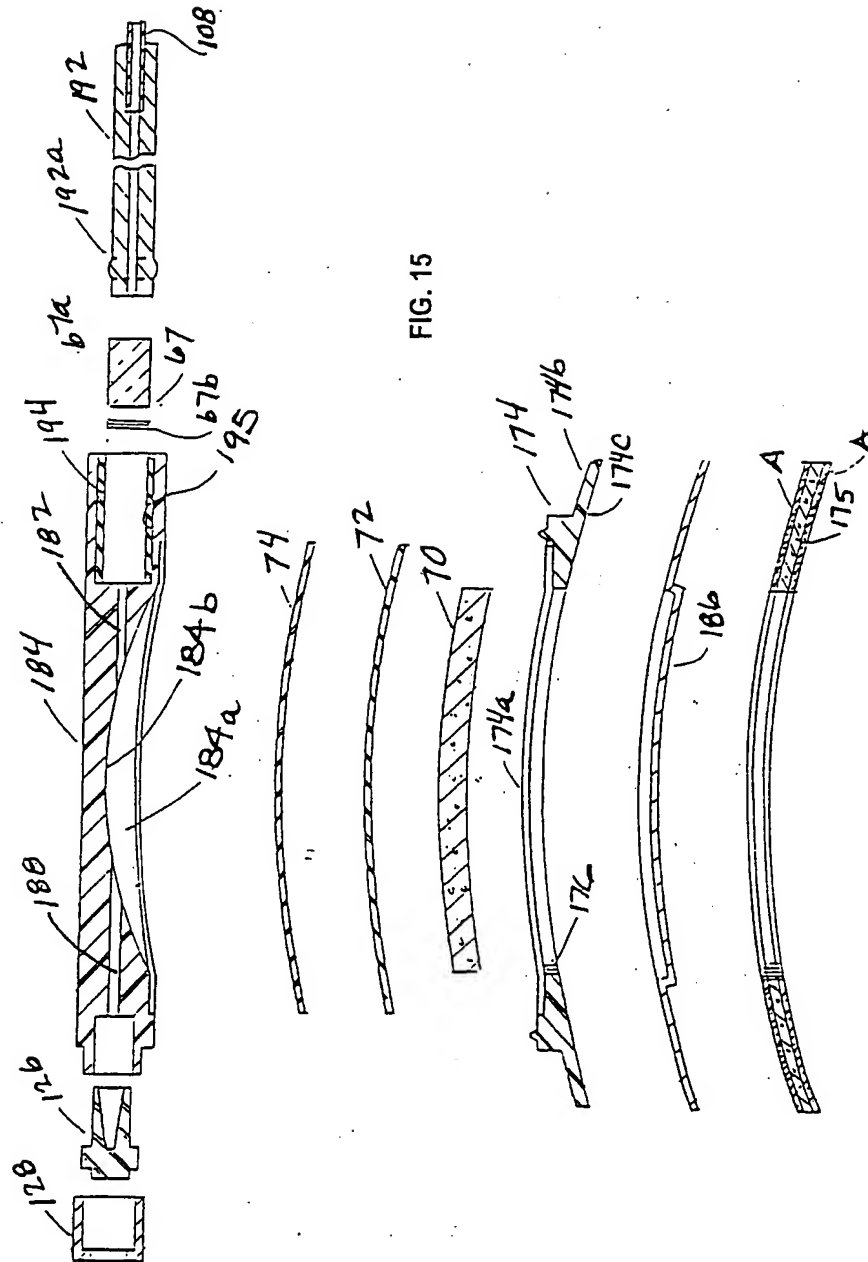
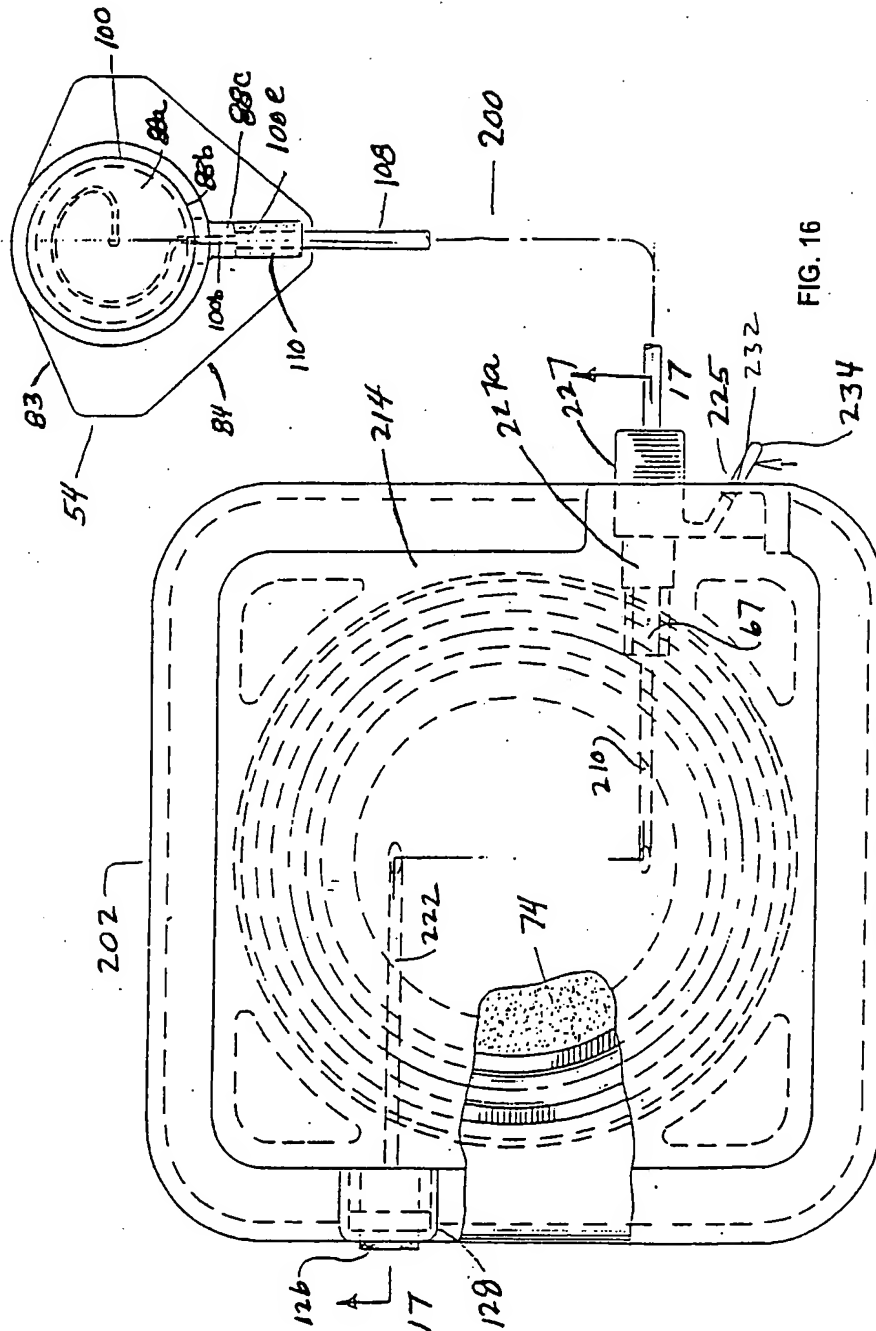


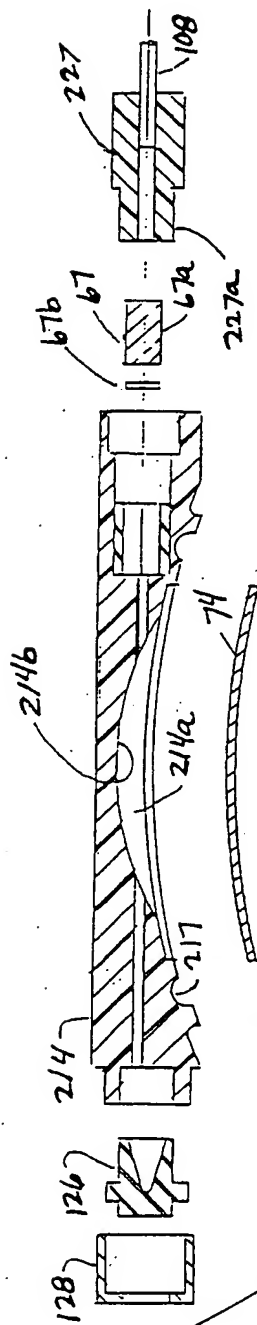
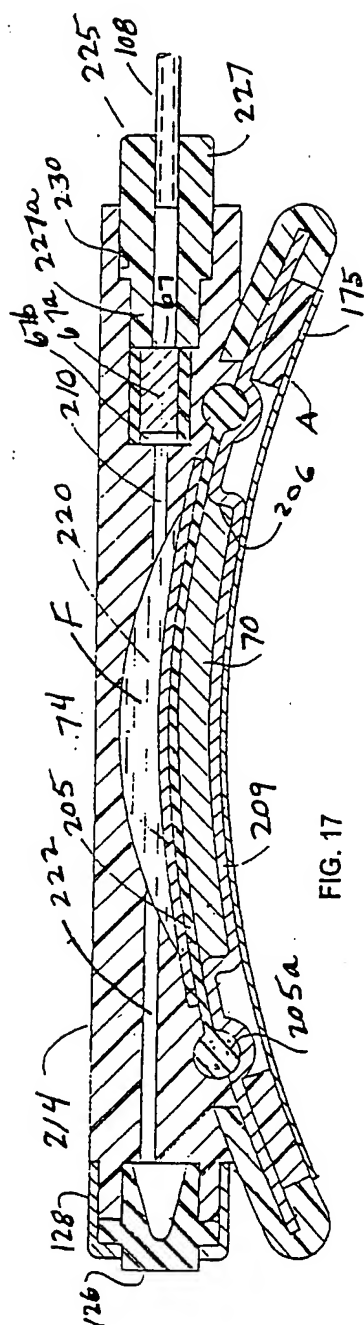
FIG. 14

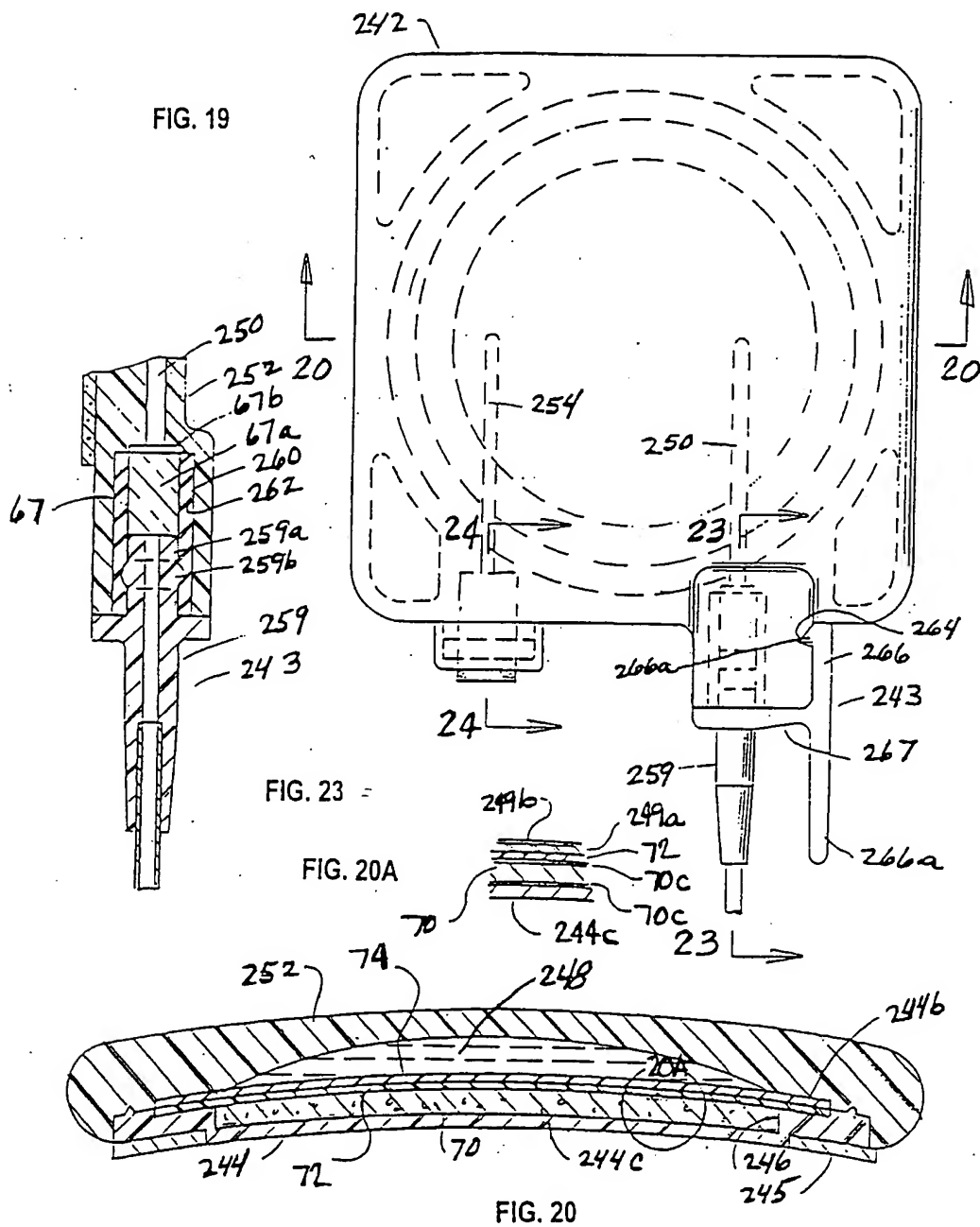




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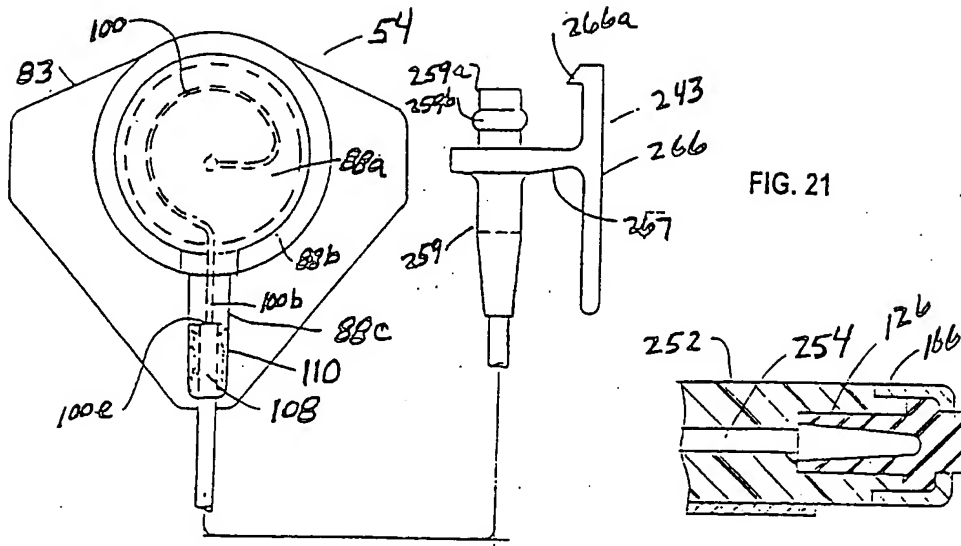


FIG. 21

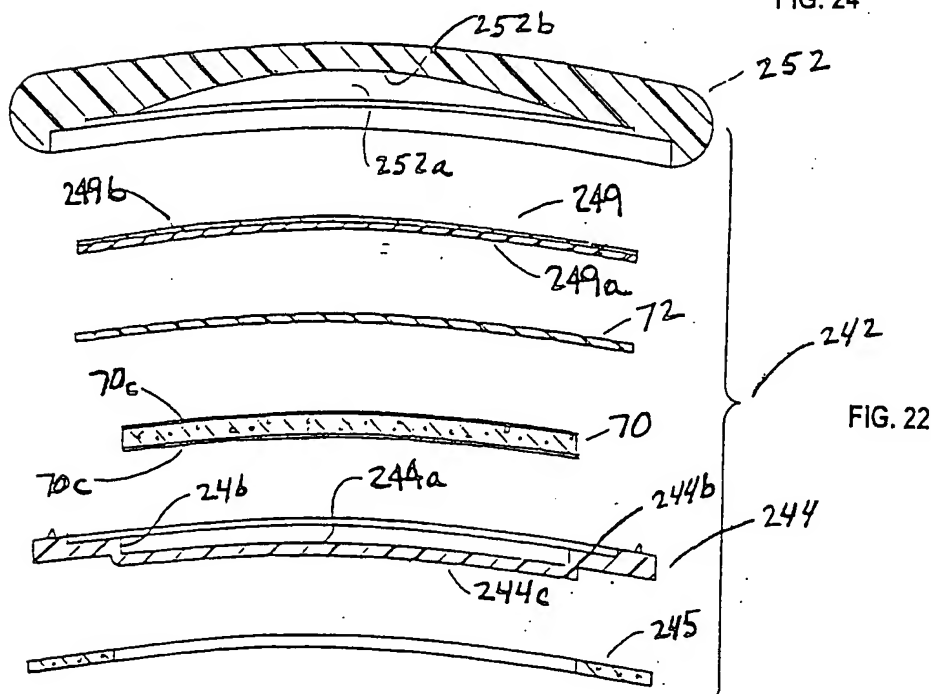


FIG. 22

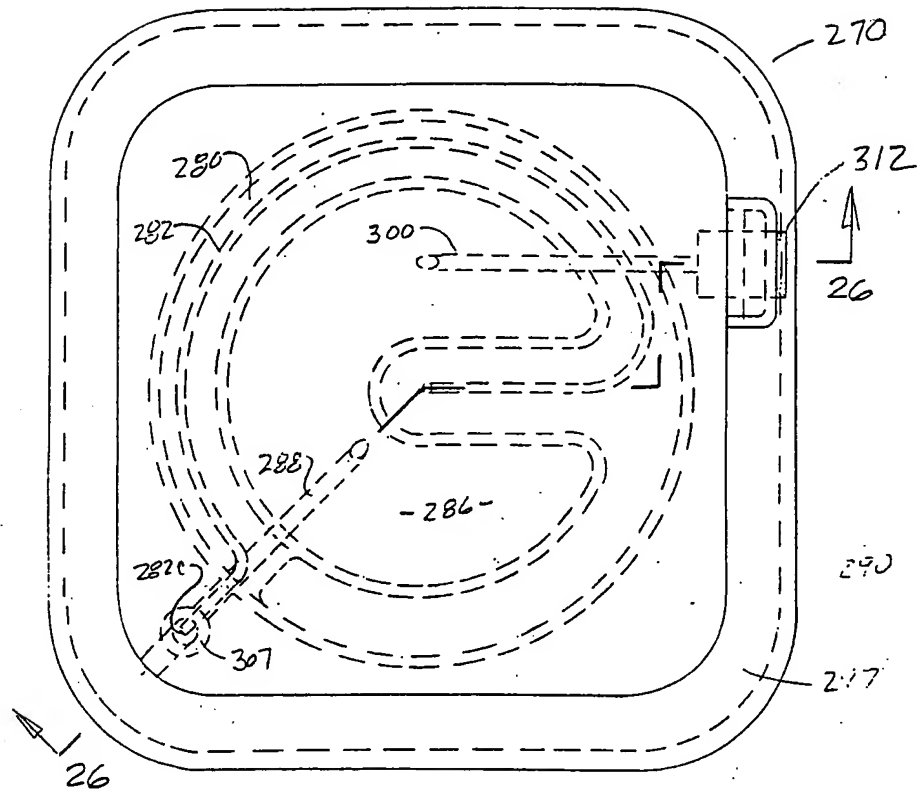


FIG. 25

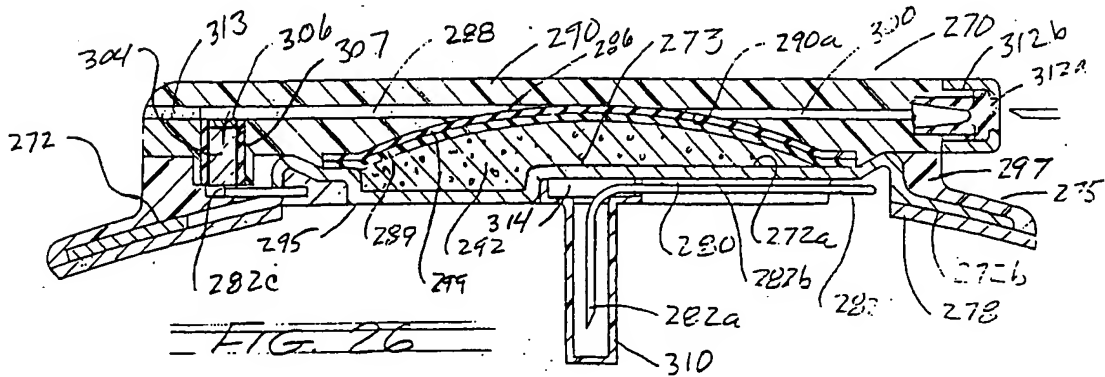
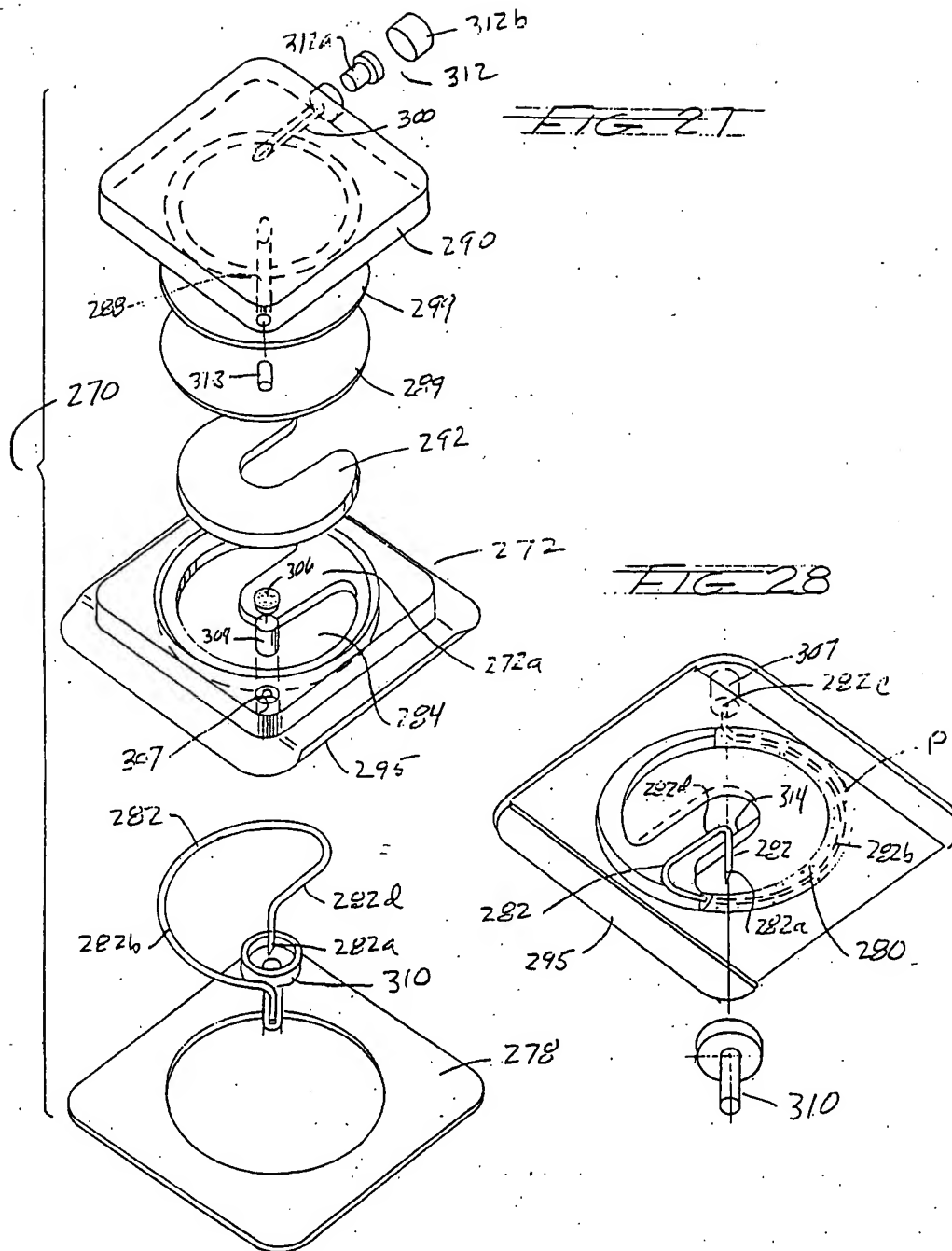


FIG. 26



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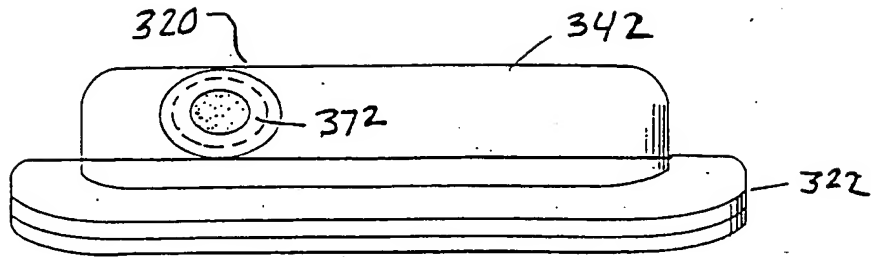


FIG. 29

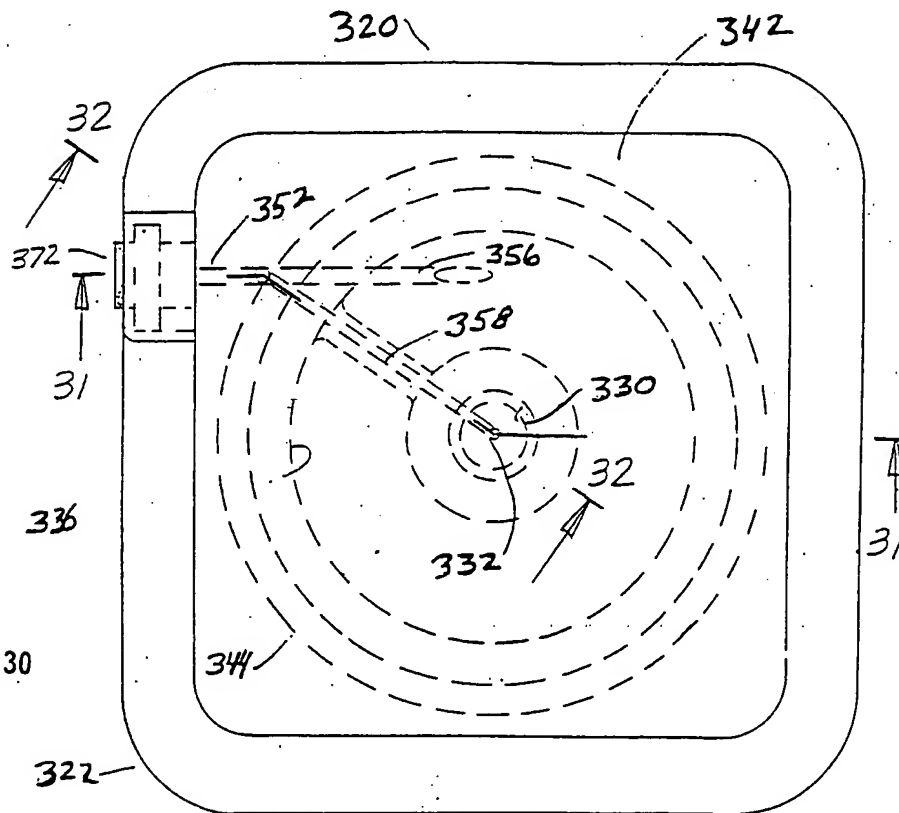


FIG. 30

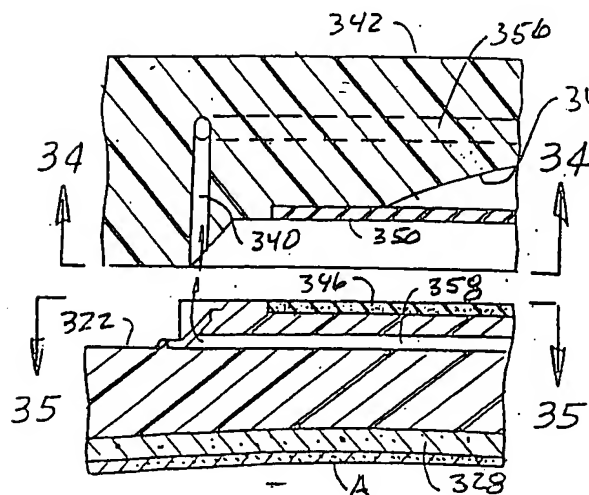
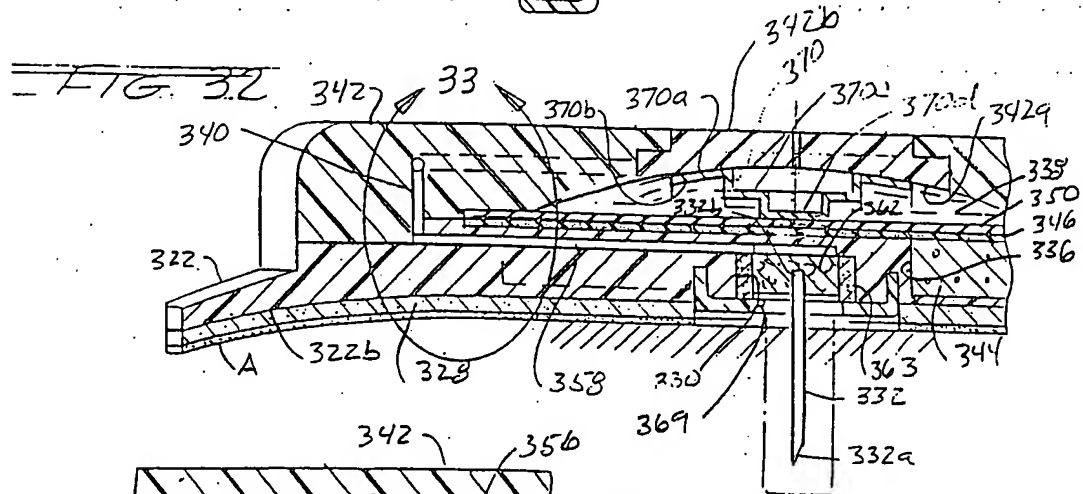
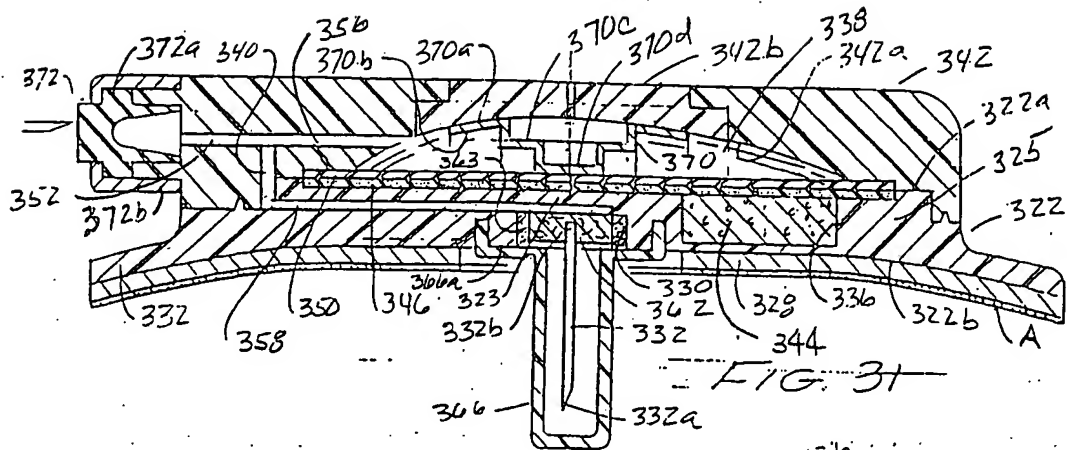


FIG. 33



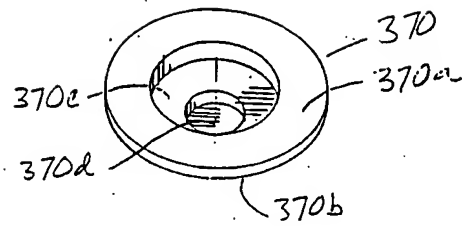


FIG 31A

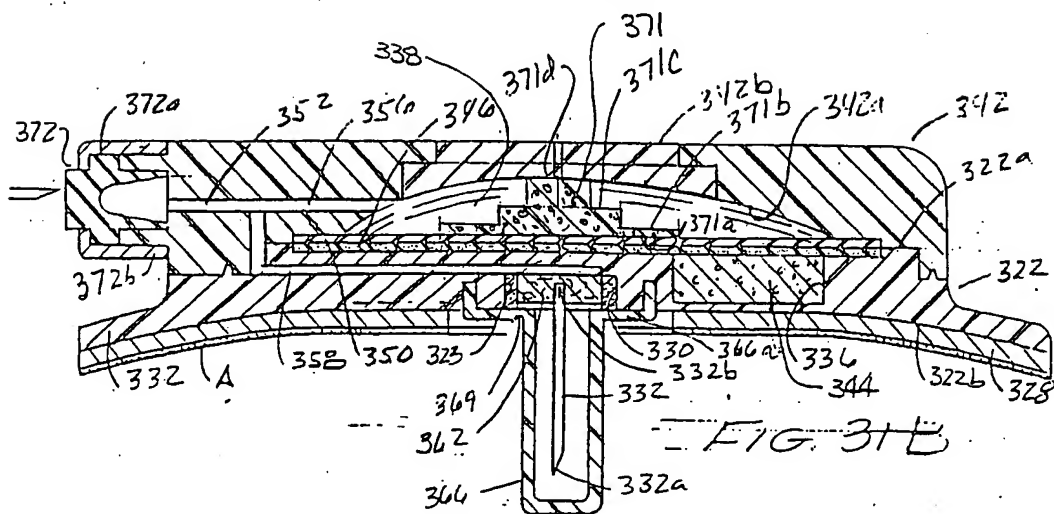


FIG 31B

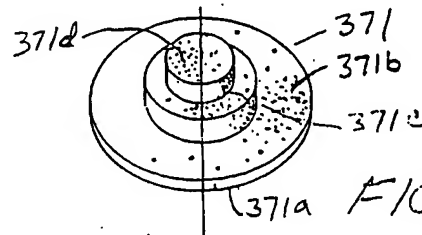


FIG 31C

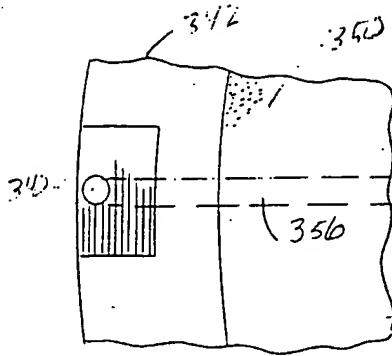


FIG. 34

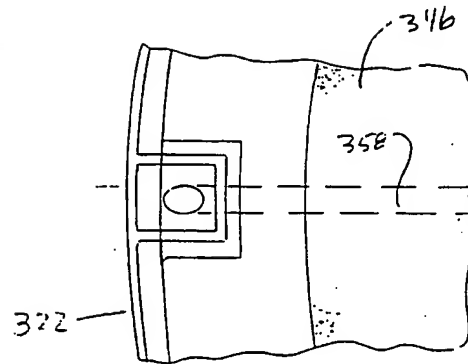


FIG. 35

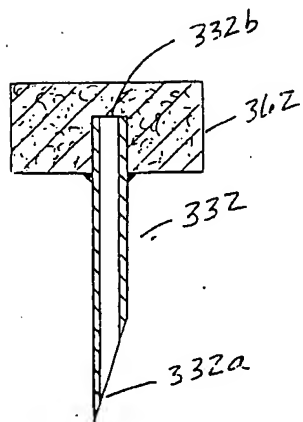


FIG. 38

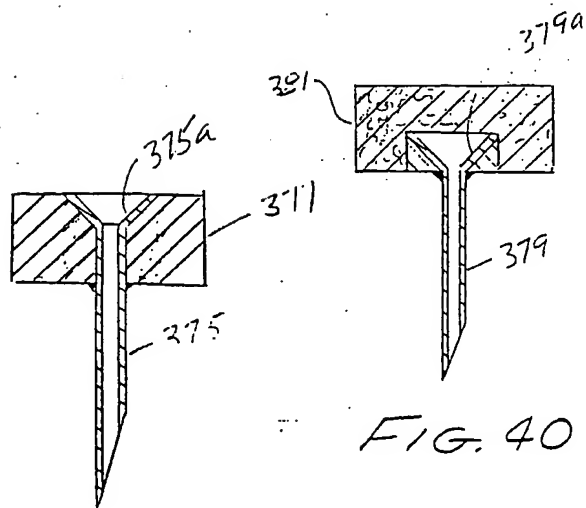
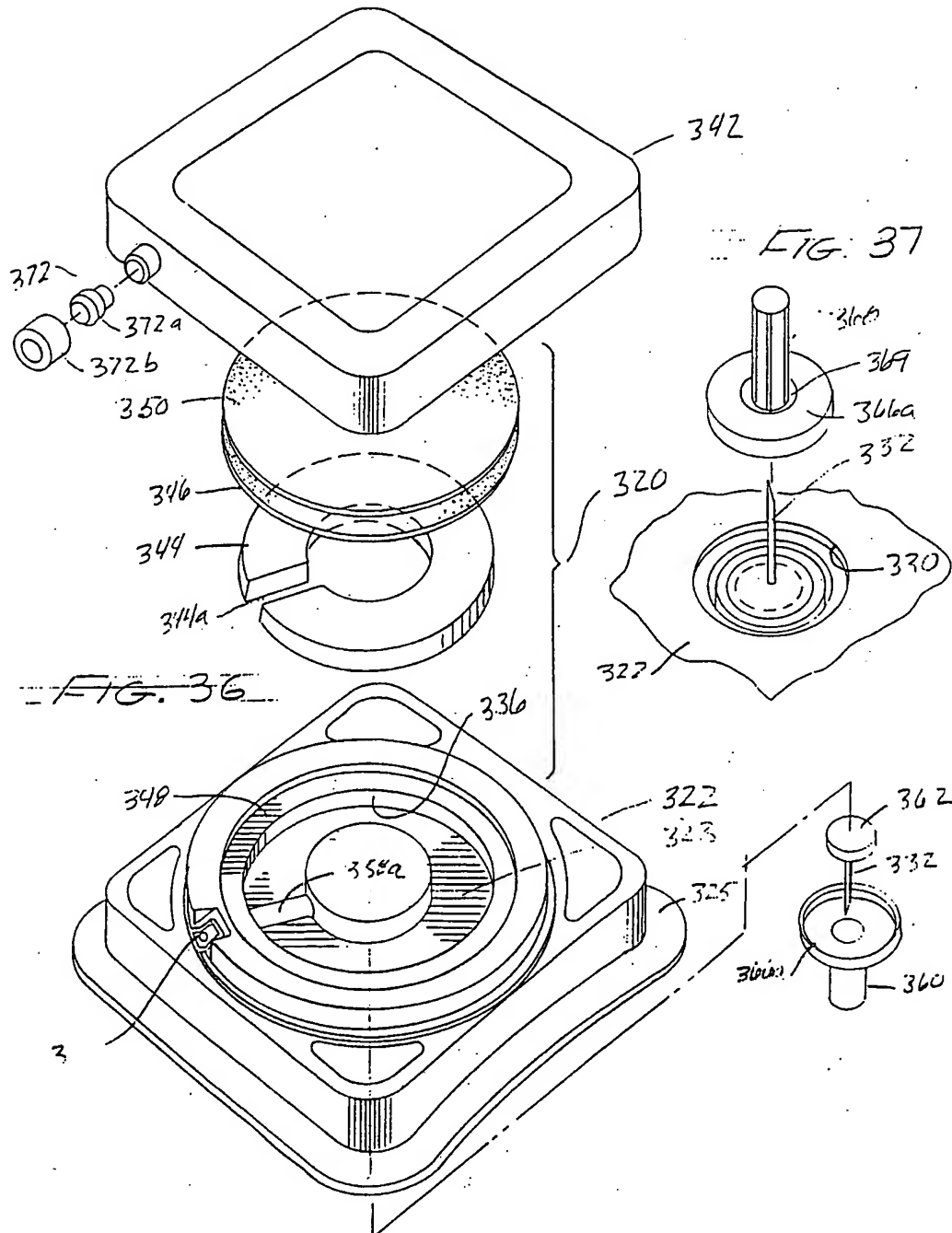


FIG. 39

FIG. 40





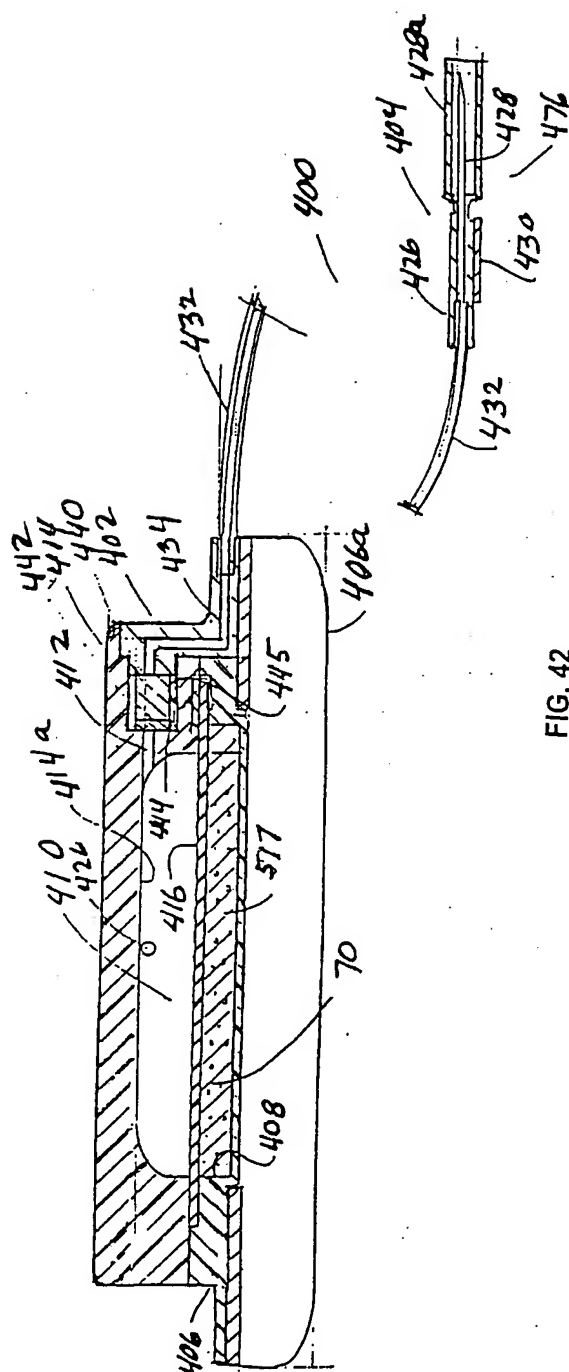
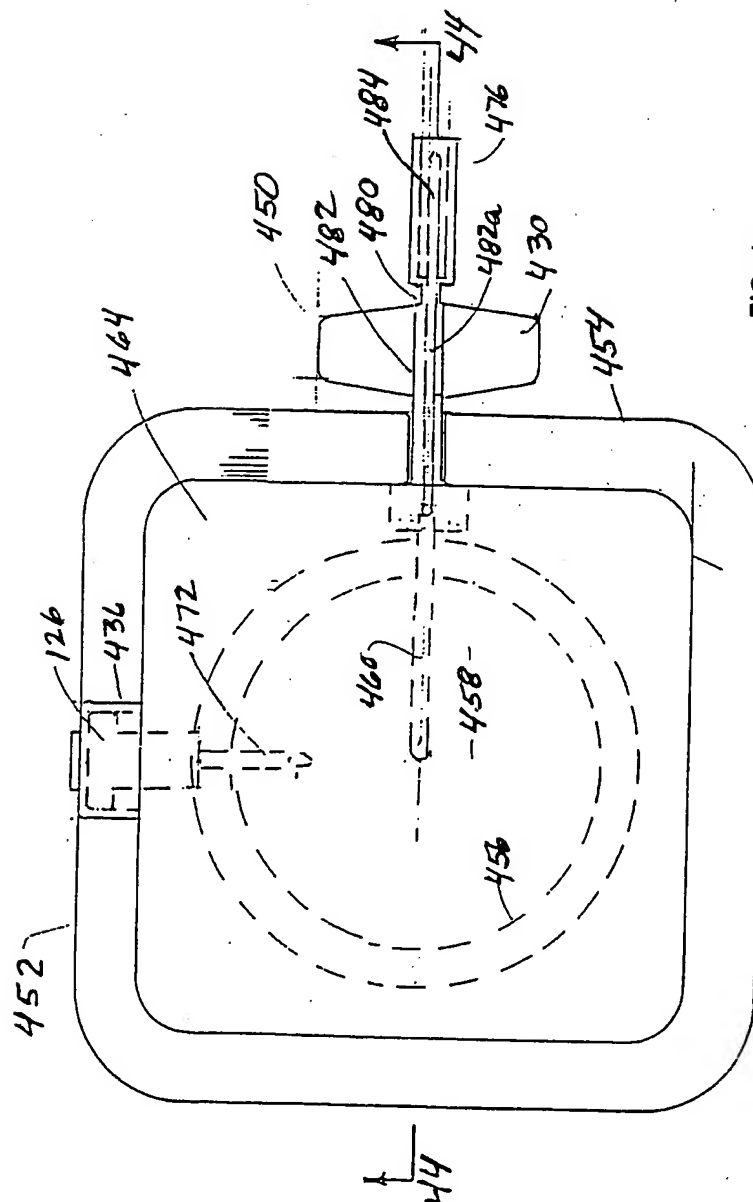


FIG. 42

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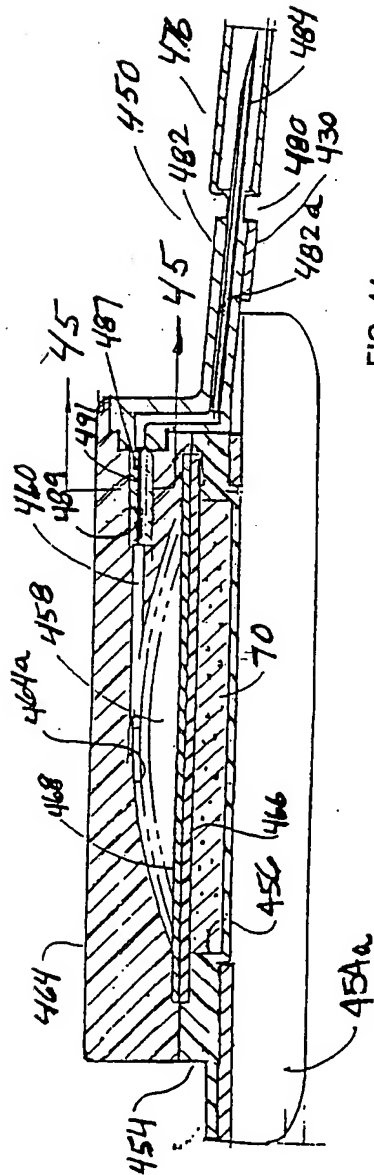


FIG. 44

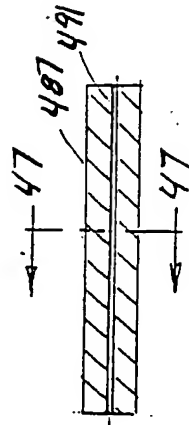


FIG. 46

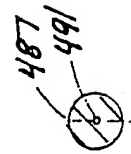


FIG. 47

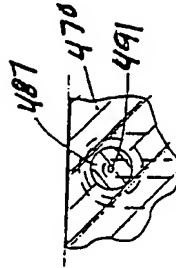


FIG. 45

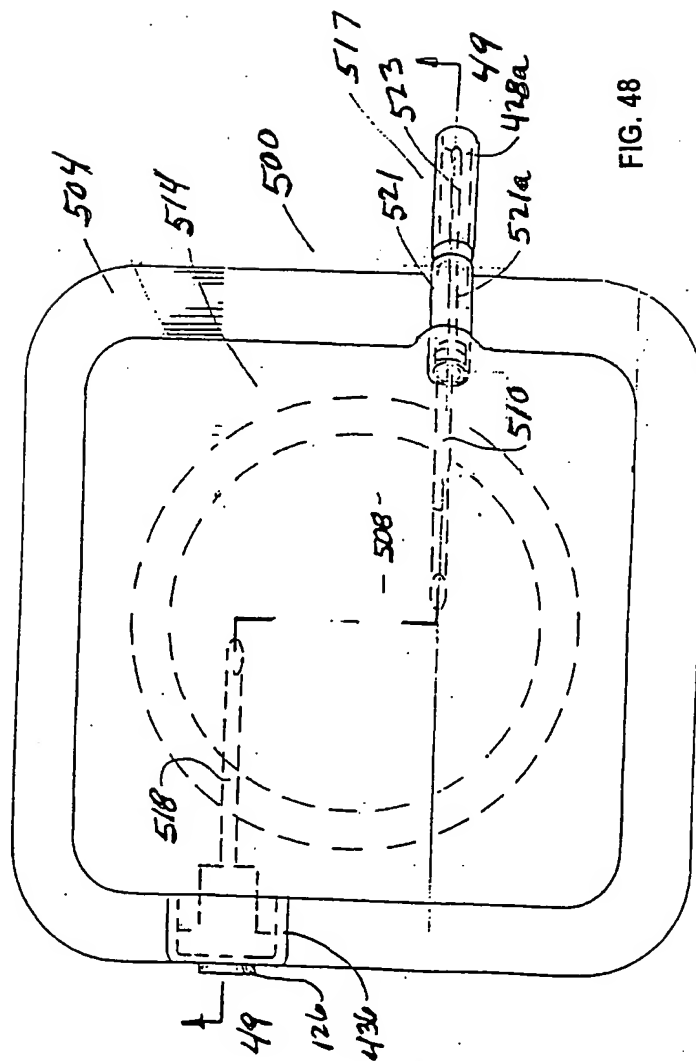


FIG. 48



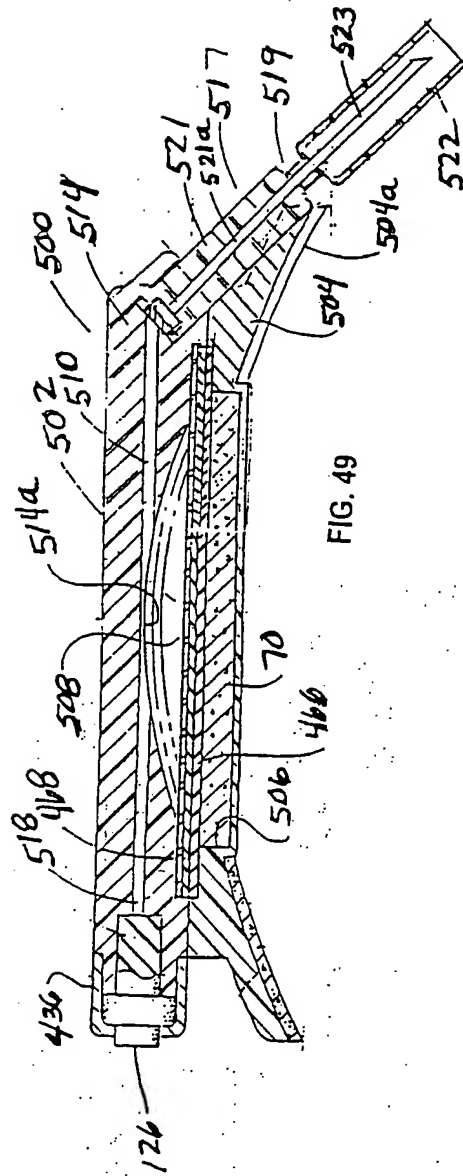
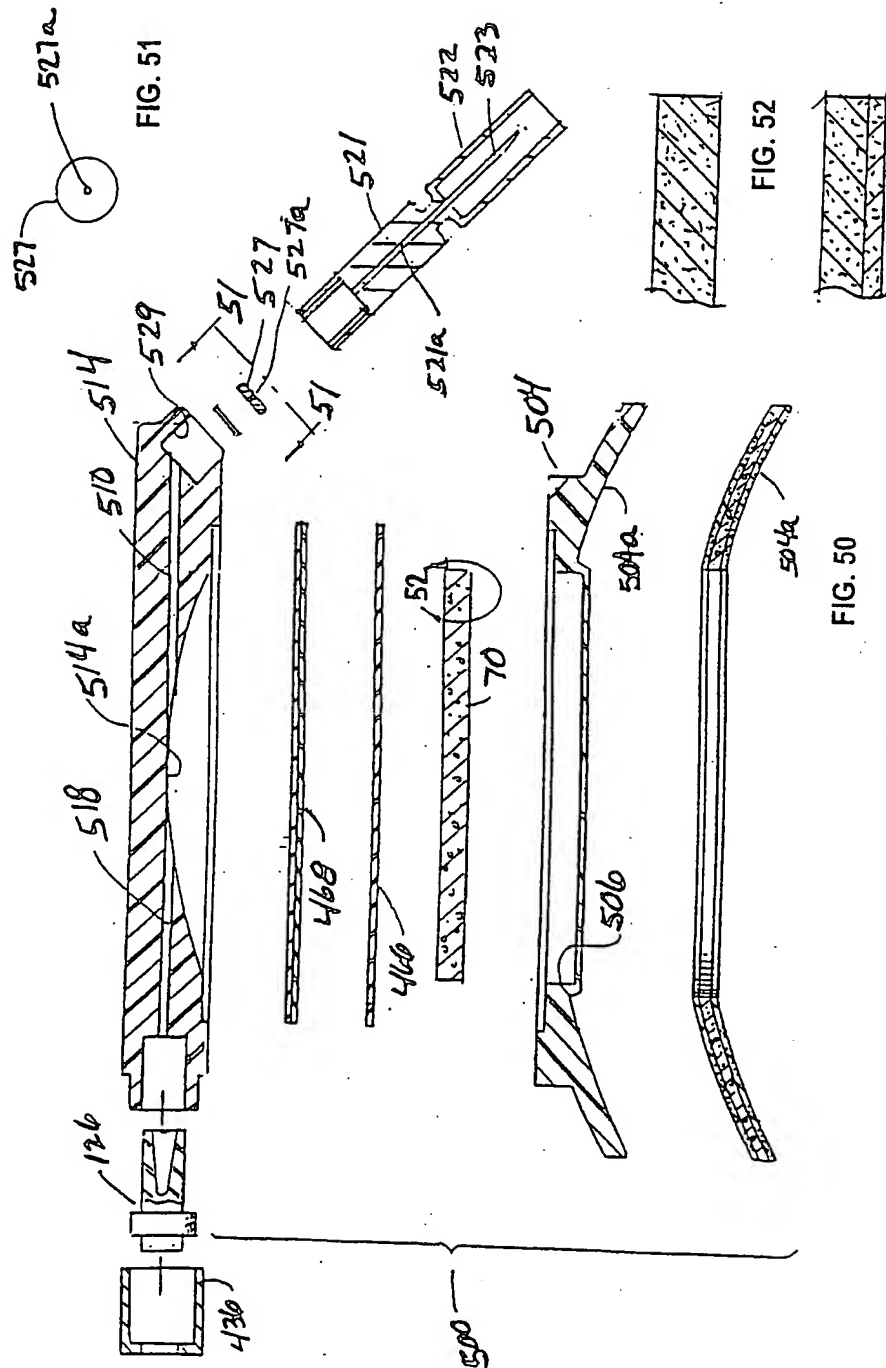


FIG. 49



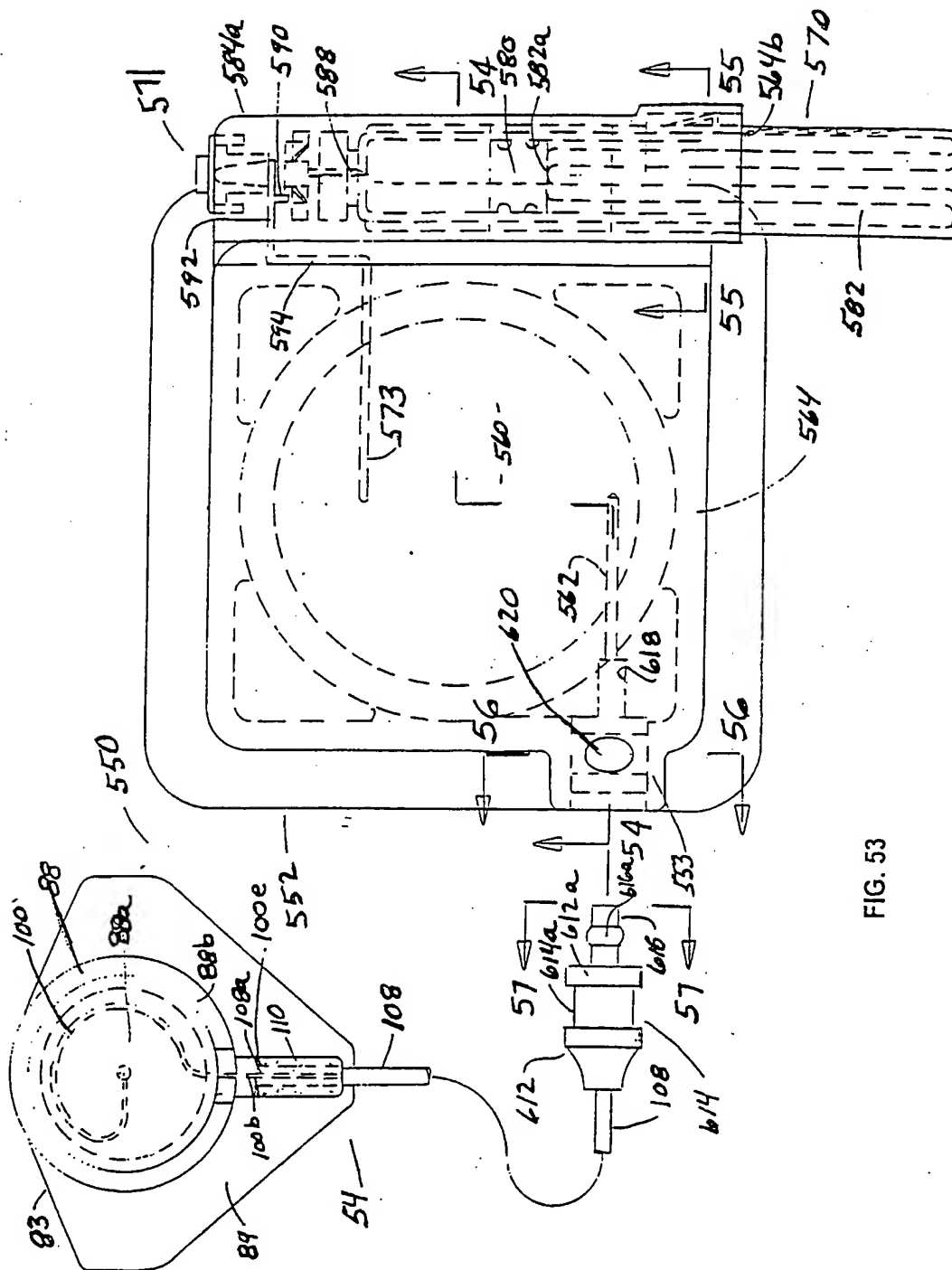


FIG. 53

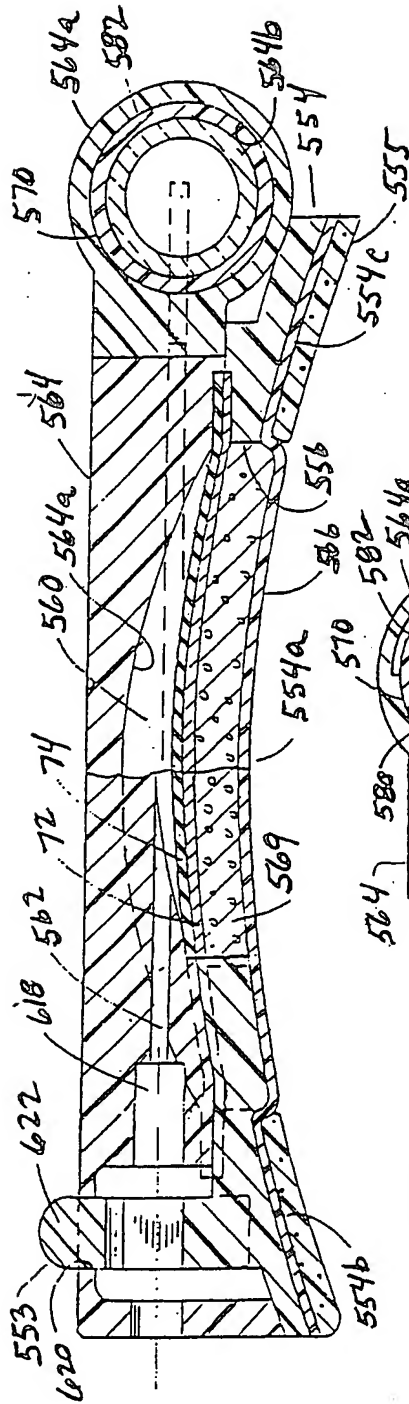


FIG. 54

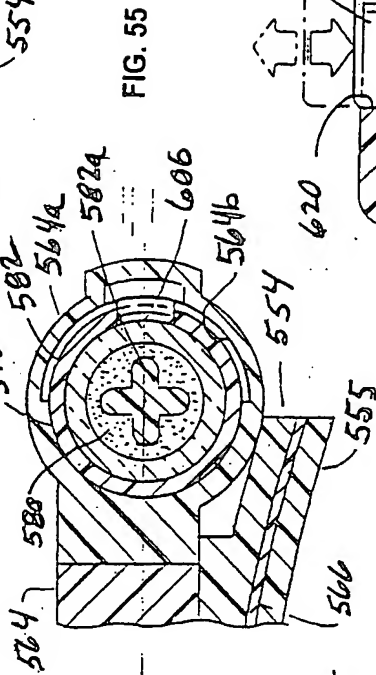


FIG. 55

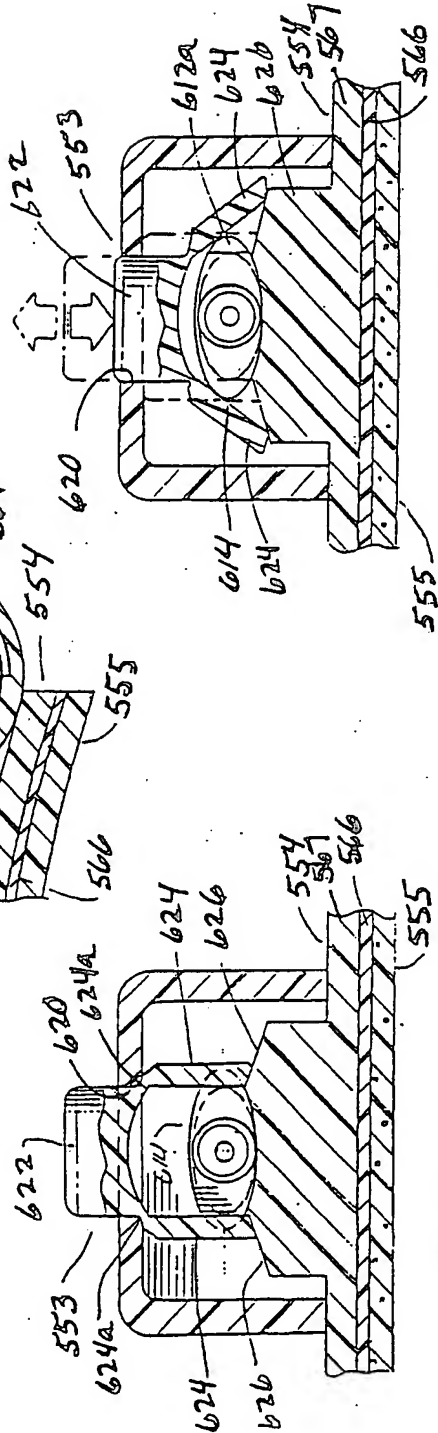


FIG. 56

FIG. 56A

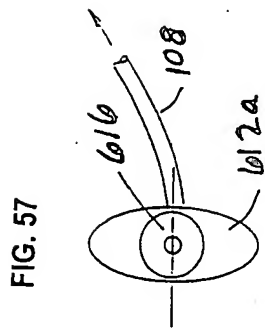
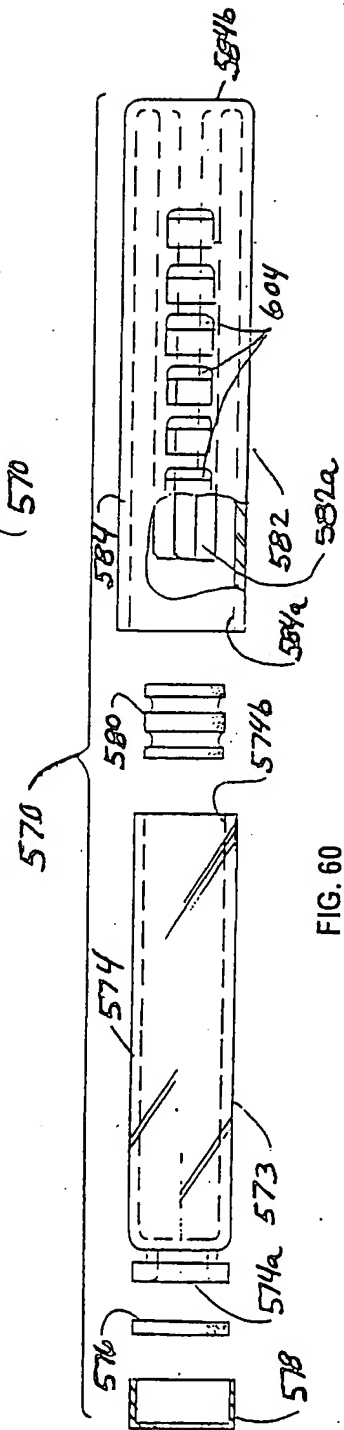
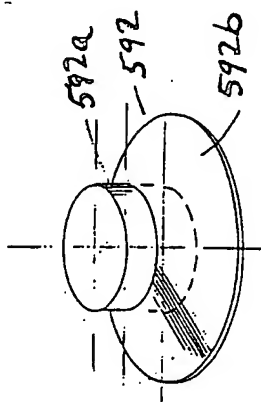
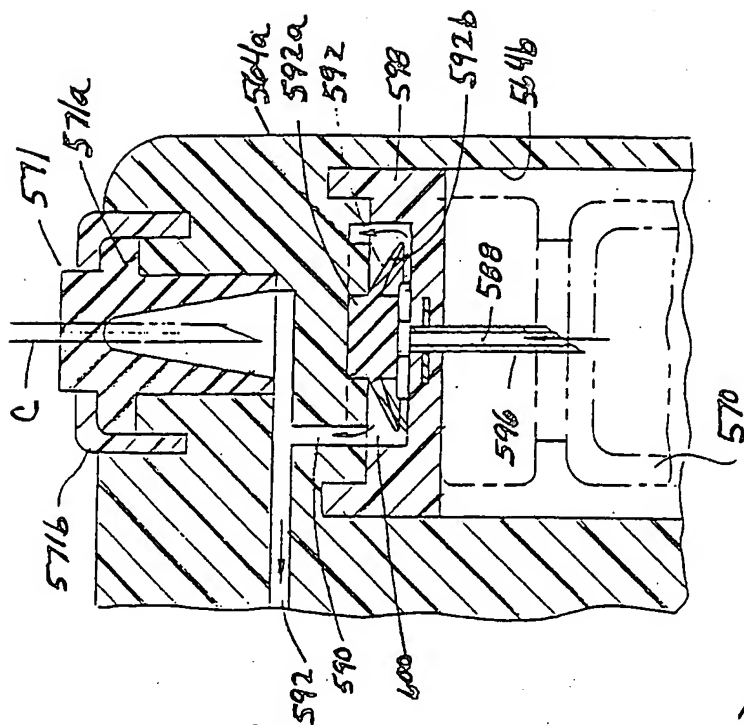
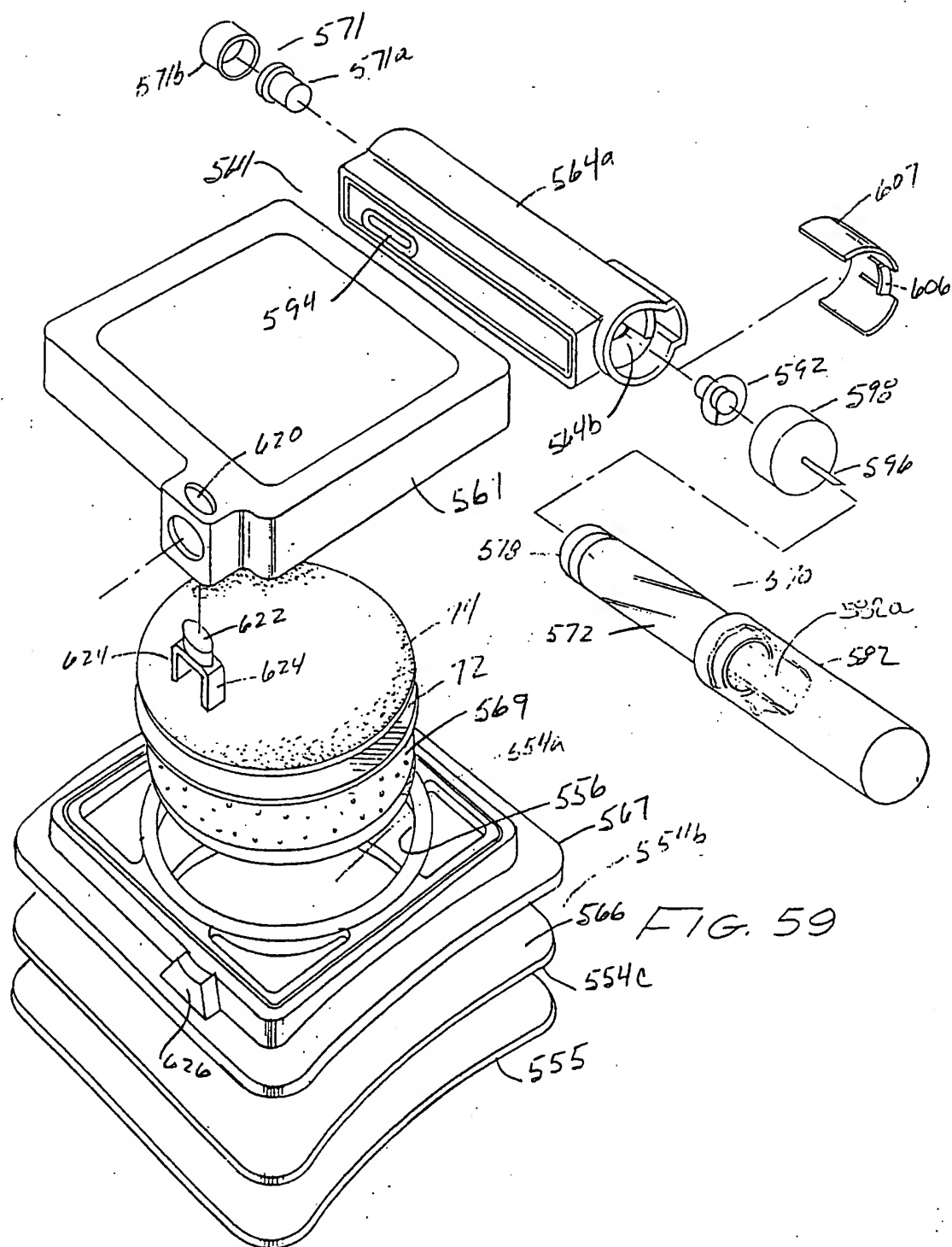
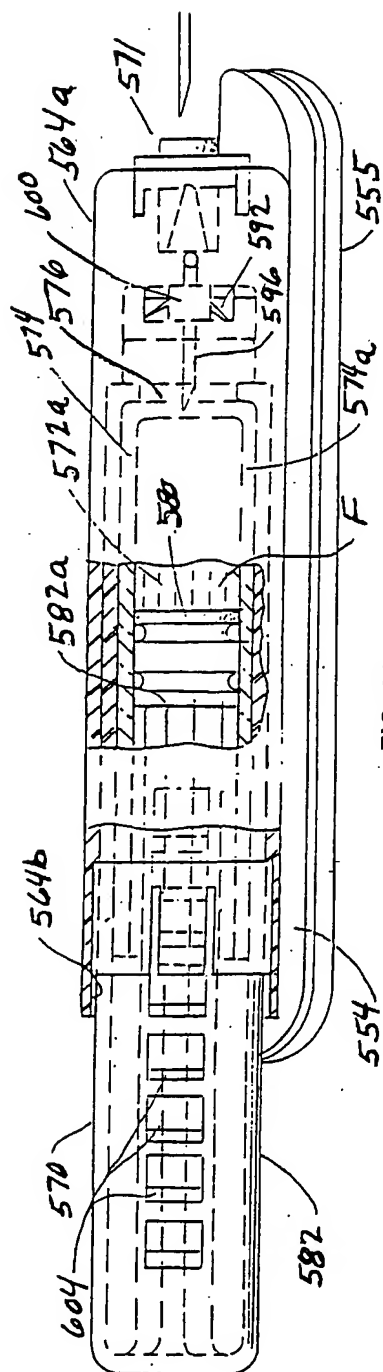


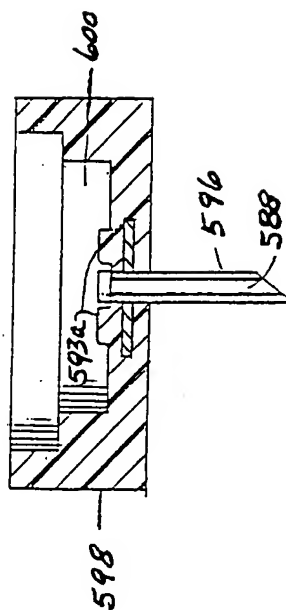
FIG. 58



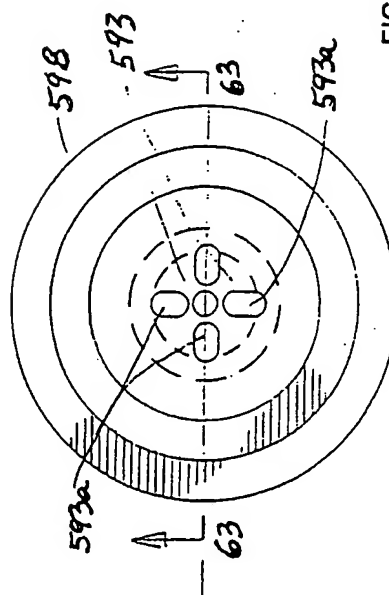




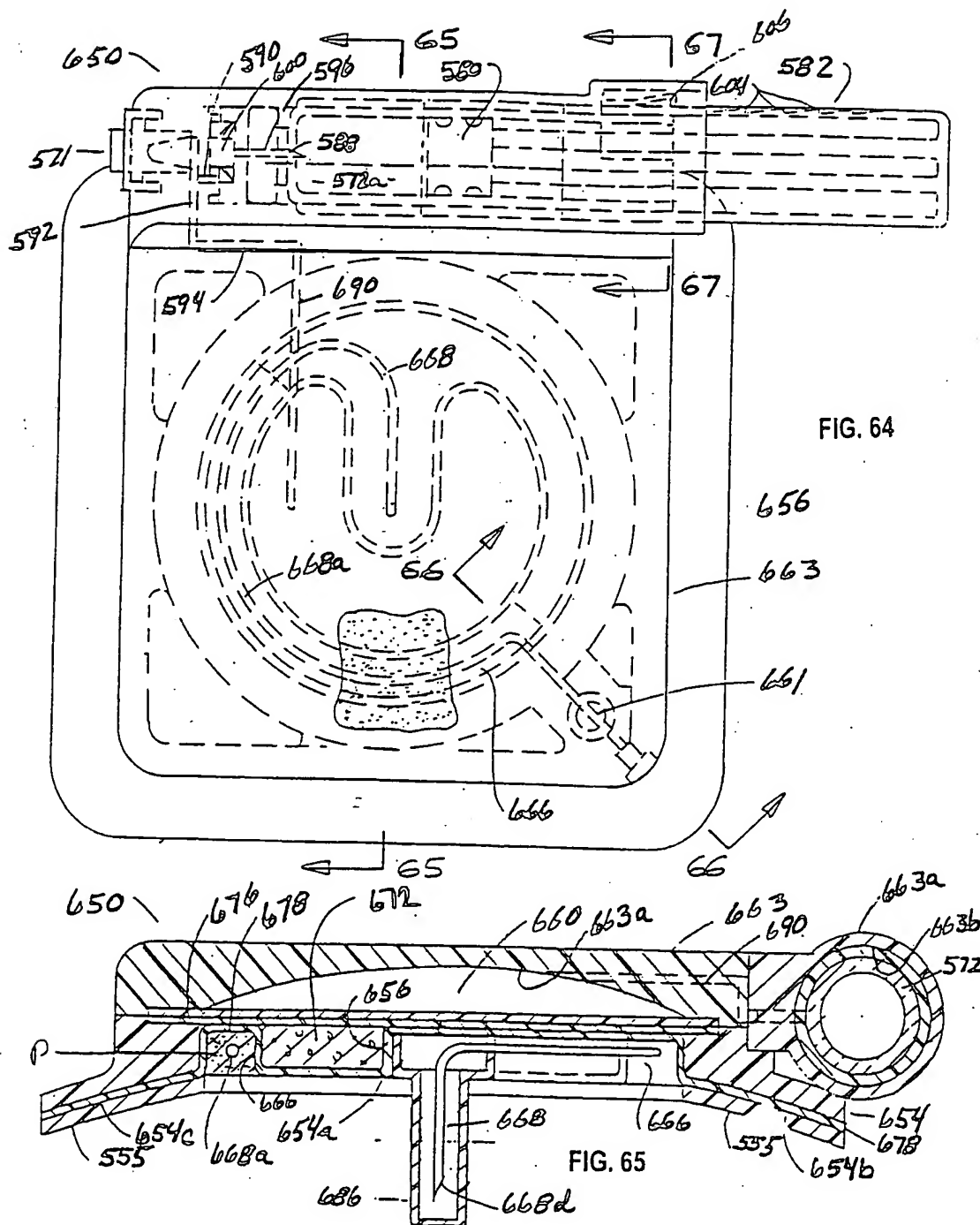
**FIG. 61**



**FIG. 63**



**FIG. 62**





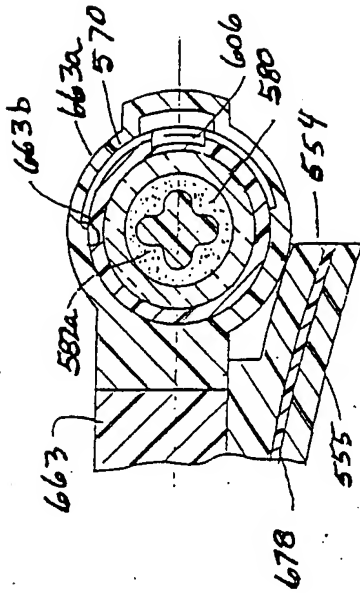


FIG. 67

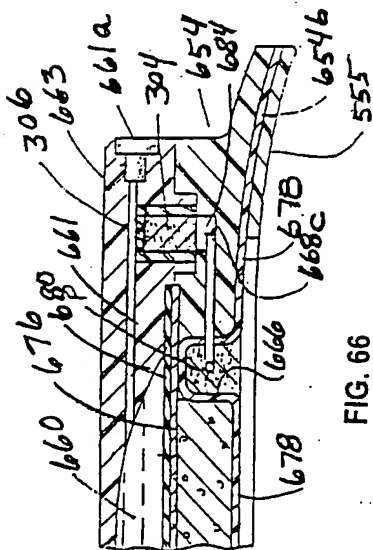


FIG. 66

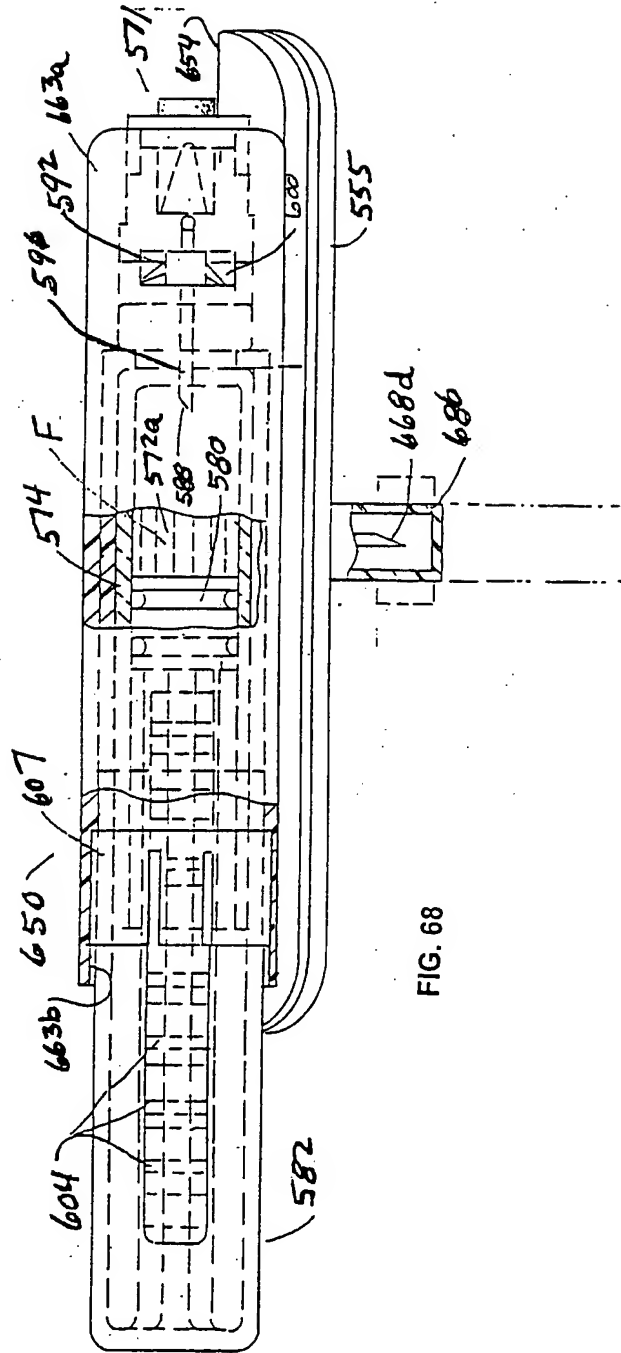
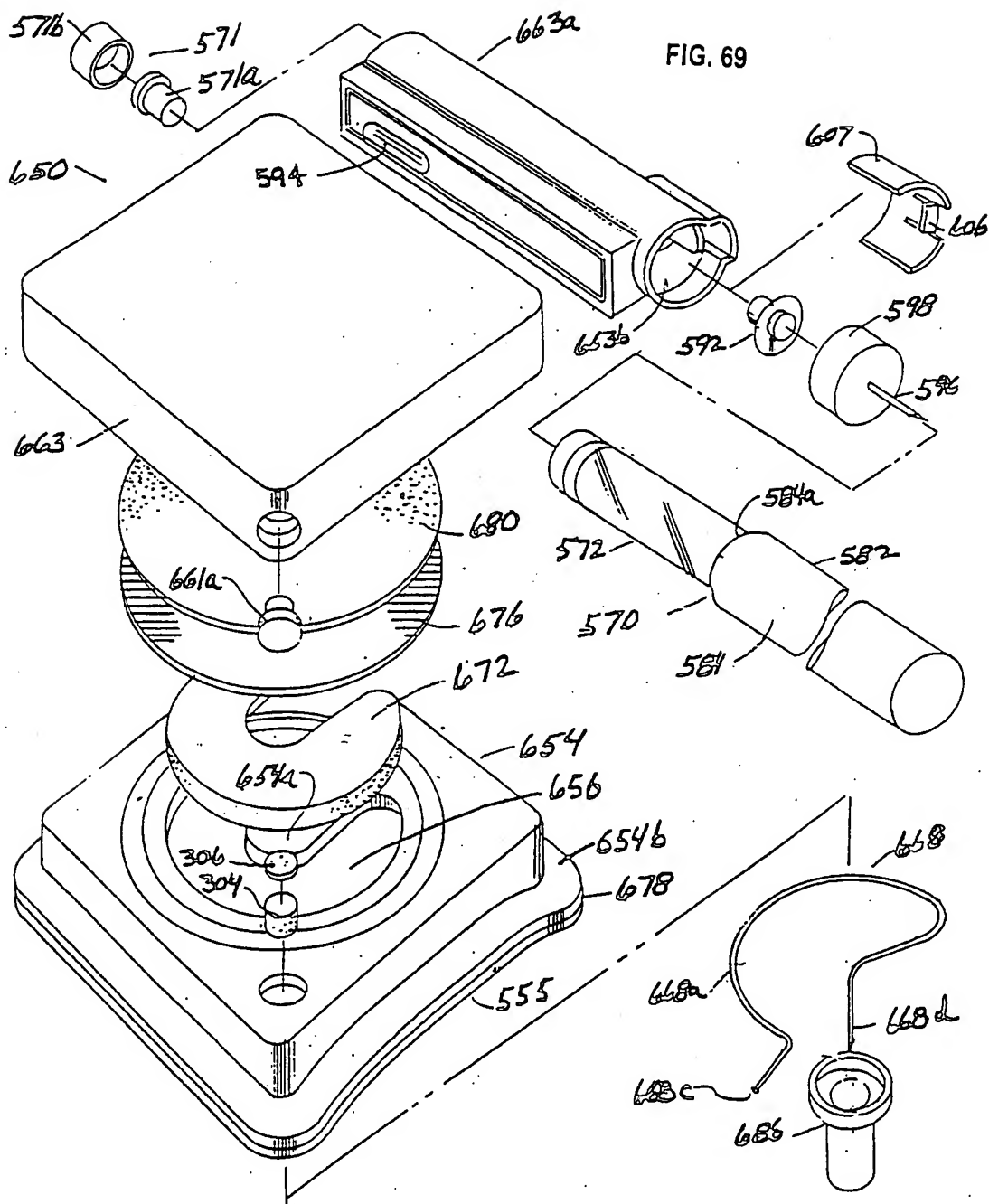


FIG. 68



## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US98/17766

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(6) :A61M 37/00 US CL :604/132, 890.1 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) U.S. : .128/DIG. 12; 222/94-96; 604/131, 132, 151, 153, 185, 257, 259, 262, 890.1  Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) APS, IS&R		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y, P	US 5,693,018 A (KRIESEL ET AL.) 02 DECEMBER 1998, ENTIRE REFERENCE, AND ESPECIALLY FIGS. 4, 7, 17 AND 19	1-5, 11-14, 16-18, 23-29, 33-41, 46, 48, 49
Y	US 5,403,893 A (TANAKA ET AL.) 04 APRIL 1995, ENTIRE REFERENCE, ESPECIALLY FIG. 6.	1, 11, 23, 33, 46, 51
Y	US 5,368,570 A (THOMPSON ET AL.) 29 NOVEMBER 1994, FIGS. 1, 2 AND 5.	4, 17, 18, 24, 40, 41
Y	US 5,651,979 A (RON ET AL.) 29 JULY 1997, ABSTRACT, AND CLAIM 6.	1, 11, 23, 33, 46, 51
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* "A" "E" "L" "O" "P"	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance earlier document published on or after the international filing date document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed	"T" "X" "Y" "&" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art document member of the same patent family
Date of the actual completion of the international search 17 SEPTEMBER 1998		Date of mailing of the international search report 22 OCT 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230		Authorized officer ANH-TUAN NGUYEN Telephone No. (703) 308-2154